MAGIA
MEDTECH ALLIANCE

US MEDICAL TECHNOLOGY INDUSTRY

2019 MARKET STUDY

ESCP-i MAGIA Partnership
EUROPEAN CLUSTER COLLABORATION PLATFORM .eu

This initiative is part of the MAGIA project, the European Strategic Cluster Partnership (ESCP) on medical technologies, which has received funding from the European Union's COSME Programme (2014-2020).

Imprint

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As of January 31, 2019

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1. General Market Overview

US Economy

The US economy has a highly developed and technologically-advanced service sector which generates 20% of the global output.[1] Table 1 demonstrates a general overview of US social and economic key figures. [2]

	Key Figures
Population	325.8 million US$
Area in km²	9.83 Mio. km²
Capital	Washington D.C.
States	50 Federal States
Administrative Language	English Spanish (not an official administrative language)
Demographic Groups	76,6% White (18,1% Latino), 13,4% Afro-American, 5,8% Asian, 1,3% Natives (mainland), 0,2% Natives (island), 2,7% two or more ethnicities
GDP (nominal)	20.2 billion US$
Share of GDP	Agriculture 0,9%, Industry 18,9%, Services 80,2%
Population Growth	0,71%
Unemployment Rate	3,9%
National Debt	20 billion US$
Import	260.2 bllion US$
Import Partners	China 22,5%, Canada 12,9%, Mexico 12,7%, Japan 5,6%, Germany 4,8%
Export	213.8 billion US$
Export Partners	Canada 18,1%, Mexico 17,4%, China 7,8%, Japan 4,5%, Germany 3,5%
Import Sectors (%)	Capital goods 26.7%, Consumer goods 26.2%, Industrial goods 22.6%, Motor vehicle industry 14.8%, Food & Beverages 5.7%, other 4%
Export Sectors (%)	Capital Goods 33.4%, Consumer Goods 13.4%, Industrial Goods 31%, Automotive Industry 10.4%, Food & Beverage 8%, other 3.5%

[1] Source: Focus Economics (2018), United States Economy Overview, retrieved on 13.12.2018
[2] Source: United States Census Bureau (2018): Quick Facts United States und U.S International Trade in Goods and Services, retrieved on 13.12.2018

1.1. An Introduction to the US medical technology industry

The medical technology industry is a vital part of the healthcare sector and is a very competitive landscape. The global market size of the medtech industry generates an estimate of 430 billion US$ annually, with established centers in the United States (US) and Europe. Trends, however, show that China is to become a more prominent player in the coming years.[3]

The United States remains a driving force in the medtech industry with the largest market in the world. The US industry for medical device manufacturing in 2018 generated a revenue of 39.5 billion US$ with a profit of 1.8 billion US$.[4] It is home to primary division leaders such as Johnson & Johnson Medical Devices & Diagnostics and General Electric Health.[5] The expected annual growth from 2018 to 2023 is 3.0%.

Even though the US is experiencing strong domestic growth, the expected revenue of 11.9 billion US$ made in exports, is projected to fall annually by less than (>) 2%. With China on the rise and continued globalization, the industry will experience a shift in the next five years. International companies will increasingly outsource manufacturing and research and development, thus reducing the number in domestic operators.[6]

Through market capitalization and sector rotation, bigger tech companies are expanding into the industry of health services. Medtech market capitalization outpaced the broader markets of the healthcare sector. Hence, the medTech industry is undergoing a transition, adapting to fundamental shifts in reimbursement, consumer empowerment and digital enablement.[7]

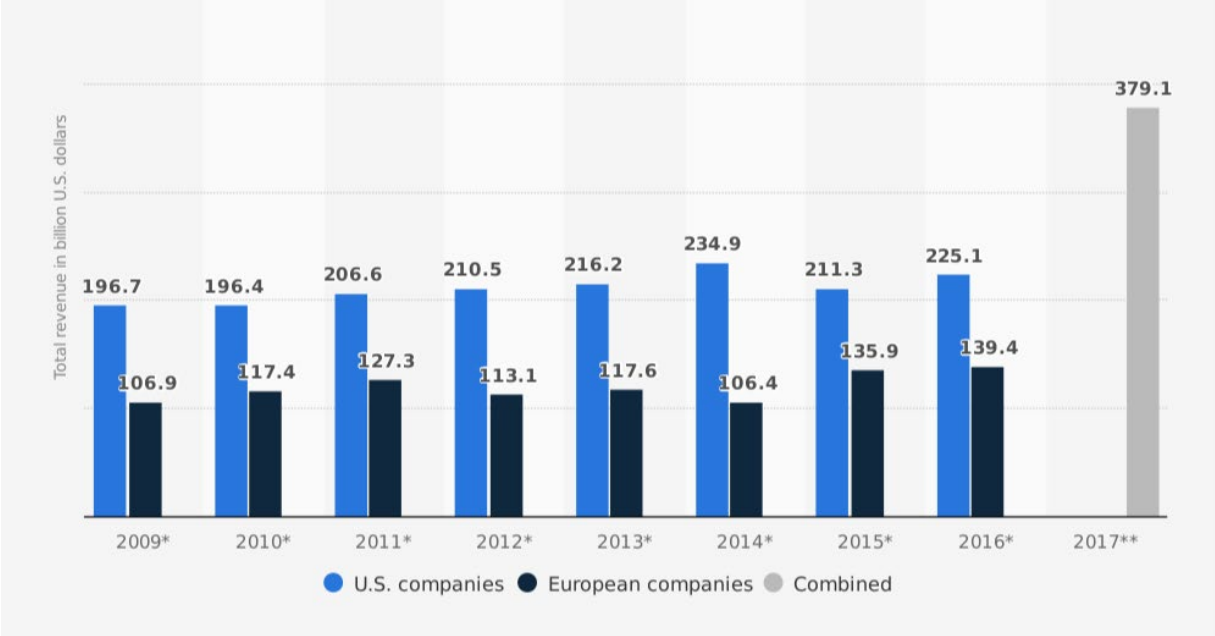
The companies are globally respected for their innovative and advanced technology.[8] 80% of American medical device companies are small and medium enterprises and consist of fewer than 50 employees. Overall, the US medtech industry sector employs over 2 million people. According to the 2016 Top Markets Report on Medical Devices, the US exported 43.2 billion US$ and imported an estimate of 49.9 billion US$ in medical devices.[9]

The top companies of the medical device industry are located in the US and generate the highest revenue worldwide. US companies produce up to 50 % more revenue than that of their European competitors. In 2017 the US medtech industry made

[3] Source: Statista (2018) Medical technology industry, retrieved on 03.01.2019
[4] Source: Statista (2018), Leading U.S. medtech regions, retrieved on 12.12.2018
[5] Source: Statista (2018) Medical technology industry, retrieved on 03.01.2019
[6] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[7] Source: EY (2016), Pulse of the Industry, retrieved on 13.12.2018
[8] Source: International Trade Administration (2016),2016 Top Markets Report Medical Device, retrieved on 07.01.2018
[9] Source: International Trade Administration (2016) 2016 Top Markets Report Medical Devices, retrieved on 07.01.2019

225.1 billion US$ in revenue. Figure 1 shows the total revenue of US and European medical technology companies from 2009 to 2017 in billion US$. Both markets combined generated a revenue of 379.1 billion US$ in 2017.

Figure 1: Total revenues of US and European medical technology companies



Source: Statista (2018) Total revenue of US and European medical technology companies from 2009 to 2017 (in billion US$), retrieved on 15.04.2019

1.1.1. Export and Import of Medical Devices

Traditionally, the medical device manufacturing industry is known for in-house sourcing. Shifts in the medtech industry are driving experienced companies to outsource to niche companies though. Stronger profit margins allow for general tech companies to invest in facility infrastructure and specialize in equipment to manufacture their own medical devices.

With a globalizing world, the trend for many companies is to move production to other countries as to minimize transaction cost. Moreover, in place of exporting, medical devices that are produced outside the US are manufactured to comply with regulations and quality controls of that country. Even though, the regulatory framework of medical devices is being more and more coordinated under the direction of the World Health Organization to allow easier access to different national markets and uphold standards, each country applies an altered framework.

As illustrated in Table 2, manufacturers in the medical technology industry operate in the area of in-vitro diagnostic substance, electro-medical apparatus, irradiation apparatus, surgical and medical instruments, surgical appliances and supplies, dental equipment and supplies and ophthalmic goods.

Table 1: Trade flows of Medical Devices 2015

Sectors	2015 Exports (Billion US$)	2015 Imports (Billion US$)
In Vitro Diagnostic Substance	6.1	3.5
Electro-medical Apparatus	7.5	10.3
Irradation Apparatus	3.6	3.7
Surgical and Medical Instruments	12.4	12.3
Surgical Appliances and Supplies	9.6	13.7
Dental Equipment and Supplies	1.2	1.3
Ophthalmic Goods	2.7	5.1
Total	**43.2**	**49.9**

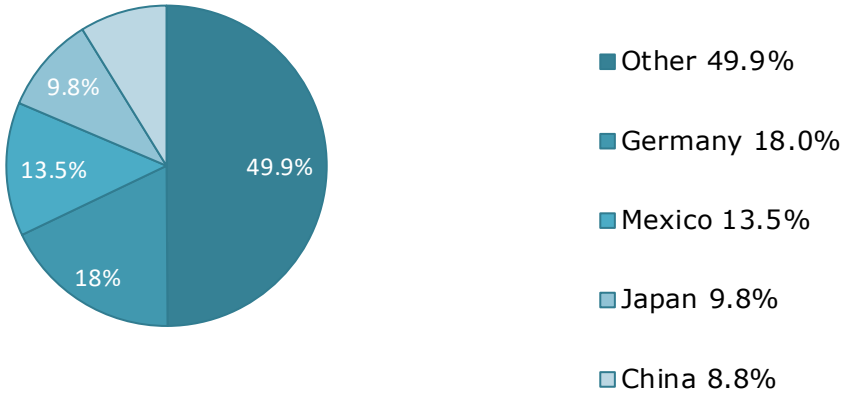
In 2017 the US export of medical devices exceeded 41 billion US$ in key product categories.[10] The result of emerging markets is a decrease in exports at an annual rate of 2% valued at 11.9 billion US$ and an increase of imports at an annual rate of 4.0% with 17.3 billion US$ over a five year span to 2018.

Because many manufacturers are establishing operations abroad, countries no longer need to import devices from the US. Emerging markets such as China and Singapore made significant progress and are investing in their own medical device manufacturing industry. 3D bio-printing is a technology that is especially on the forefront of product development and receives significant attention from Asian countries, thus decreasing dependence on the US for scientific research.

Figure 2 and 3 highlight China as one of the strongest trade partners to the US for medical devices. Yet the highest importing country to serve the US market is Germany which further receives in return 9.5% of the exports from the US.[11]

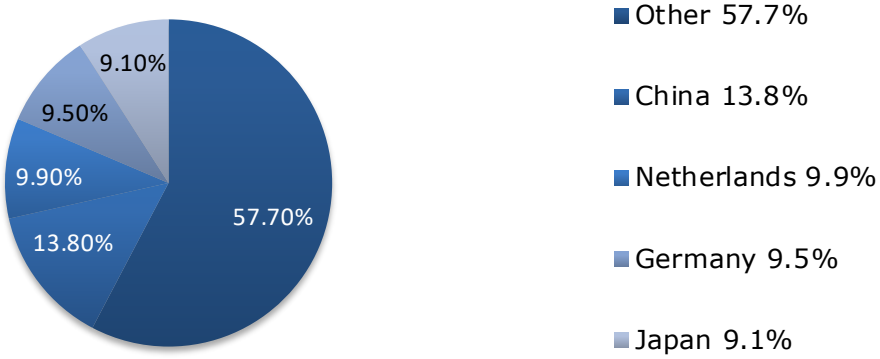
[10] Source.: International Trade Administration (2016),2016 Top Markets Report Medical Device, retrieved on 07.01.2018
[11] IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

Figure 2: Imports



Total 11.9 billion US$

Figure 3: Exports



Total 17.3 billion US$

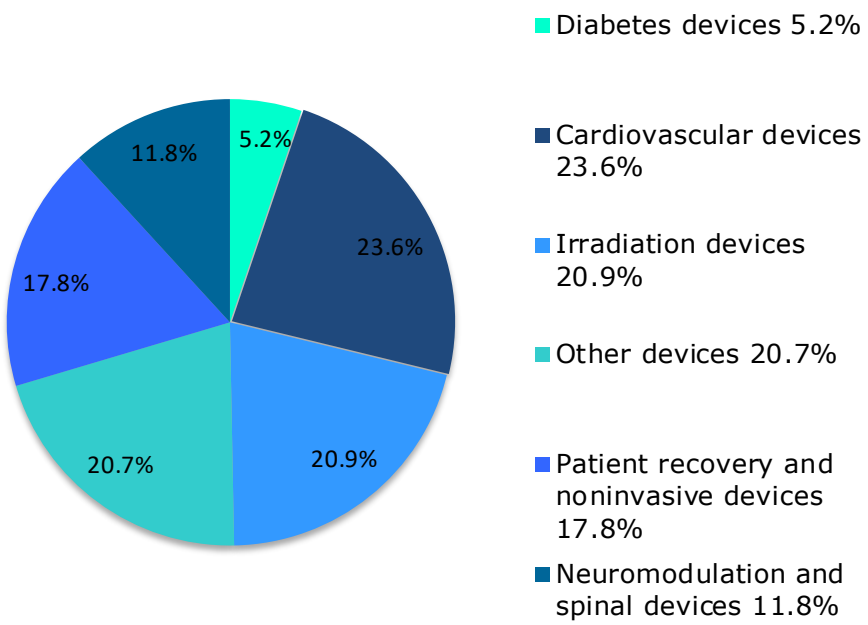
The medical device industry is a highly competitive market with various small innovative niches. Many companies have a similar product line and overlap in specific

sectors. With the market being saturated, bigger companies use their advantage to sell a product at a better bargain price to hospitals and other end-consumers.[12]

Even though small and medium sized companies do not necessarily have the monetary reserves comparable to their larger competitors, their focus on niche markets provides them with an advantage to produce specialized medical devices and thus can incorporate bigger corporations as a buyer. This approach allows the number of operators in the industry to grow annually over the next five years at an estimated rate of 1.9% to 927 operators by 2023, consequently pushing industry employment at an annually rate of 2.4% to 94,864 individuals.

The products and service segmentation in Figure 4, presents the estimated industry revenue of the sectors for diabetes devices, cardiovascular devices, irradiation devices, patient recovery and noninvasive devices and others, that together form a total revenue of 39.5 billion US$.

Figure 4: Products and service segmentation 2018



Total 39.5 billion US$

Source: IBISWorld[13]

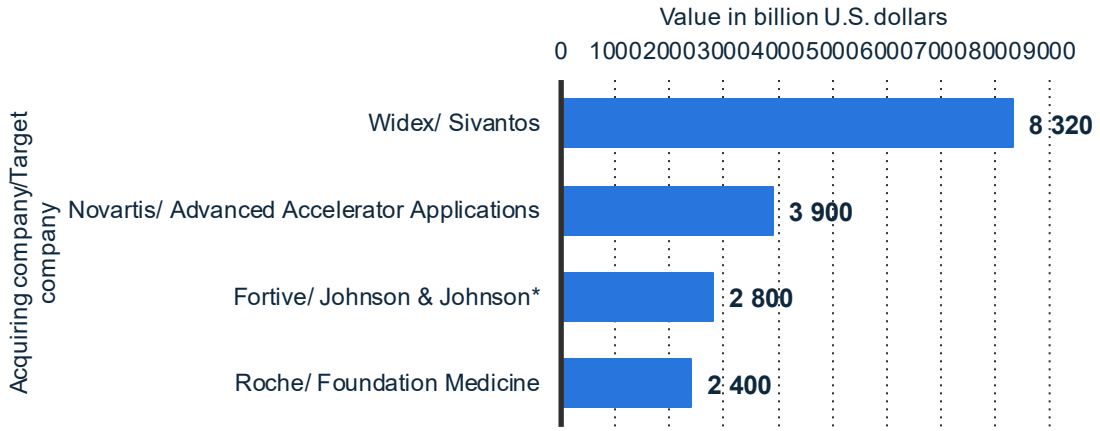
[12] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[13] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

Digital MedtTech is one of the new emerging trends according to an executive of a MedTech association. It has a broad proposition covering multiple areas of innovation all characterized by new and evolving ways to generate, parse, and leverage data. Wearable and implantable diagnostics, potentially combined with therapeutic interventions that likely will be increasingly AI-driven, for example, hold great promise to continue to improve care. Diagnostics continues to play an increasingly important role in patient care. The surface in terms of precisions diagnostics, calibrating drug regimens for example to maximize their effectiveness for individuals, has only begun to be touched upon.[14]

1.1.2. Economies of scale

Important elements that influence the success of medtech companies are the size of the companies, access to new technology, access to a highly skilled workforce and contacts within key markets. Particularly companies with large manufacturing facilities are able to reduce costs and selling prices while maintaining profit margins. Through large mergers and acquisitions the big medtech companies are able to consolidate their strong position in the medical technology industry.[15]

Figure 5: Selected top medtech mergers and acquisitions worldwide in 2017-2018, by value (in billion US dollars)



Source: Statista (2018) Medical technology industry, retrieved on 17.01.2019

The biggest mergers between 2017 and 2018, as shown in Figure 5, were between Widex and Sivantos with a value 8.320 billion US$, Novartis and Advanced Accelerator Applications with a value of 3.900 billion US$ and the merger of Fortive and Johnson & Johnson with a value of 2.800 billion US$

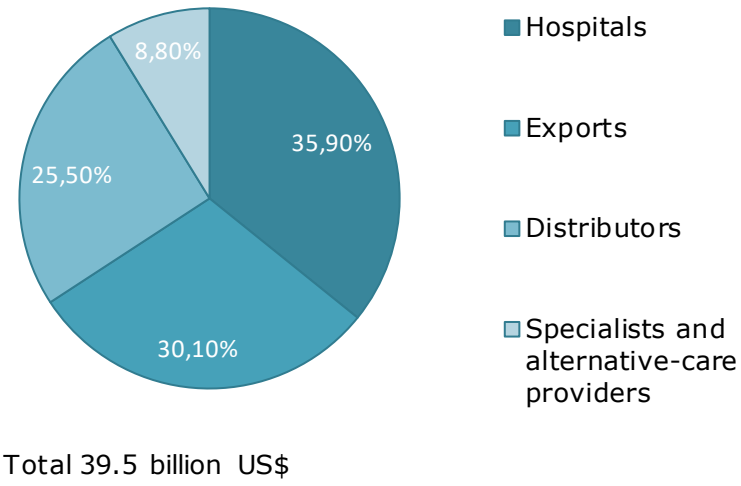
[14] Interview with an Associate of a Medical Techology Association from 10.01.2019
[15] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

1.1.3. Markets for Medical Technology

The major market for medical devices are hospitals, which account for a 35.9% share of the market. Hospitals tend to be near densely populated areas, which allow easier access for patients, as the number of physician's visits are in direct correlation with the demand for medical devices. In general, medical and surgical hospitals predominantly require specific machinery for different therapeutic areas and tend to purchase machinery and products in greater quantities. Smaller, community-based hospitals on the other hand, have slightly different needs and require various types of electro-medical and electrotherapeutic products.[16]

Distributors account for 25.2% of the medical device market and are seen as the link between medical device manufacturers and healthcare providers. Distributors are wholesalers that purchase large amounts of medical and surgical equipment from manufacturers and redistributer.[17]

Figure 6: Major market segmentation 2018



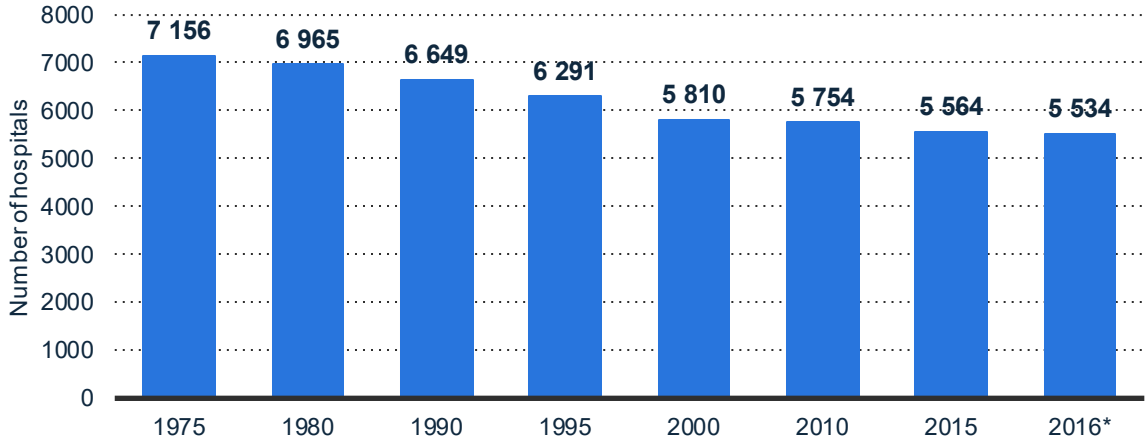
Total 39.5 billion US$

Group purchasing organizations (GPOs) are groups of businesses that are able to bargain with vendors based on their collective buying power. Especially in the health-care sector, GPOs maintain a close relationship with key distributors. The main markets for medical device manufacturers are hospitals, clinics, specialists and alternate-care providers. Long-term contracts are conducted with vendors that are able to sell on a group price.

[16] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[17] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

Figure 7 illustrates the total number of hospitals in the US from 1975 to 2016. The number of hospitals in the US has shown a steady decline. Since 2000, the number fell from over 5,800 to less than 5,600 facilities. Yet, due to US healthcare expenditures, hospitals remain one of the largest markets for the health and medical device manufacturer sector.

Figure 7: Number of all hospitals in the US from 1975 to 2016



Source: Statista (2018), Number of all hospitals in the U.S. from 1975 to 2016, retrieved on 16.01.2019

According to another specialist of a MedTech association, the fundamentals continue to be strong. There are boundless opportunities to continue to save and improve lives. The factors such as a worldwide aging population, expanding middle classes in emerging economies that are increasingly seeking the best available care, and the continued need for solutions for the world's healthcare challenges are considererd a good foundation for continued growth.[18]

1.1.4. External Drivers

Number of physician visits
One of the largest groups of medical device buyers are hospitals. The number of purchases correlates to the number of physician visits in a year and government funding. An increase in physician visits will positively affect the demand for medical devices.[19]

Number of adults aged 65 and older
With an aging population and longer life expectancy, the incidences of diseases and disorders are on a rise. In view of that, the need for early on recognition and medical

[18] Interview with an Associate of a Medical Techology Association from 10.01.2019
[19] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

treatment becomes indispensable. The number of adults aged 65 and older is expected to increase in the coming years. [20]

Total health expenditure
The total health expenditure concerns private and public spending. Healthcare funding programs are intended to enable greater funding for the replacement of medical equipment and supplies. This should allow for an increase in industry demand. [21]

Federal funding for Medicare and Medicaid
More and more people are getting access to Medicare, significantly affecting physician visits and access to treatments which is considered a positive development. Health coverage is a vital factor in the US. Medicare coverage allows patients to invest in medical devices, that otherwise would not be affordable. Federal funding for Medicare and Medicaid is expected to increase. [22]

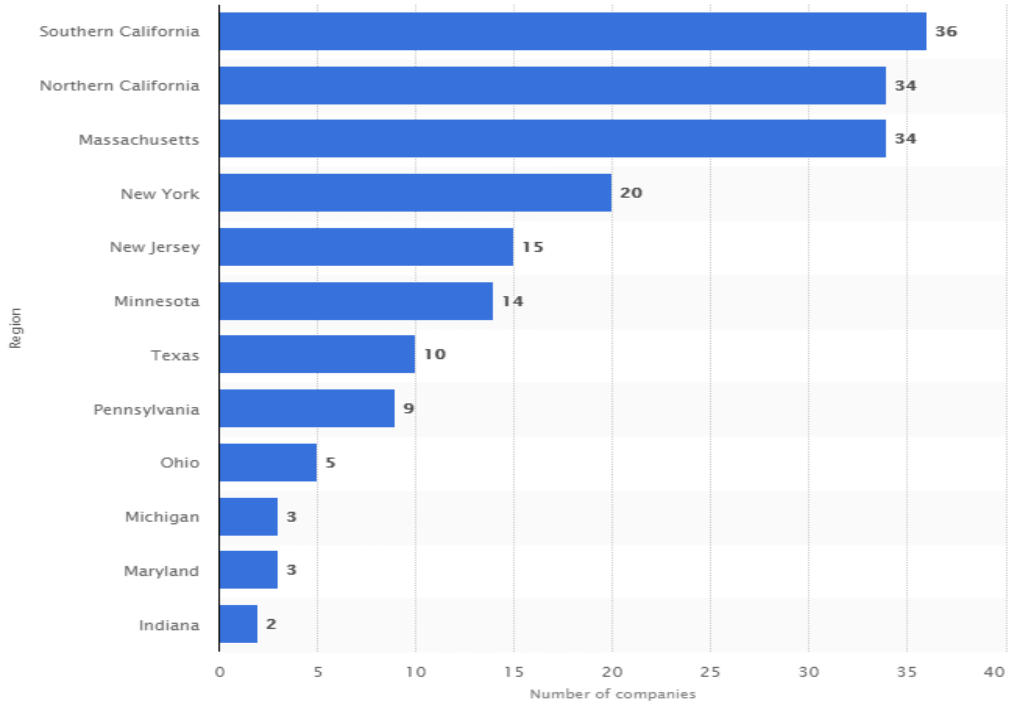
Trade-weighted Index
The trade-weighted Index is an important factor concerning the purchase of medical devices. A high trade-weighted index suppresses the purchase of domestically manufactured devices due to higher costs in purchasing. For that reason, the strong dollar poses a threat to the industry. [23]

1.1.5. Economic Growth of Medical Technology by Region

The medical technology industry is clustered across the US. Thus, different states are important to different sectors of the industry. The largest medtech hubs are found in California for medical device manufacturing and Massachusetts for its cutting edge research centers. New York and New Jersey have major academic medical institutions. As shown in Figure 8, the command centers of the world's top tech companies are located in California, Massachusetts, New York and New Jersey.

[20] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[21] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[22] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[23] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

Figure 8: Leading US medtech regions 2018



Source: Statista (2018) Medical Technology Industry, retrieved on 16.01.2019

According to Winthrop Turlow, the Executive Director of the MedTech Association, more and more companies are settling in the states around the Great Lakes, due to lower costs in production and rates in taxation. As many other small and medium sized businesses tend to settle around the Great Lakes, new smaller specialized medtech hubs are established.[24]

The distribution of medtech establishments and other high-technology industries is driven by various key factors. Thus geographic distribution, proximity to complementary industries, location of customers, suppliers, and high-skilled labor are considered important factors.[25]

[24] Interview with Winthrop Turlow, Executive Director of MedTech Association from 10.01.2019
[25] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

1.1.6. Medical Device Companies and Key distributors

Table 2 shows the top 10 global Medical Device companies based on the revenue they generated in 2018. The three leading companies in 2018 are Medtronic, DePuy Synthes and Fresenius. Overall seven of the ten medical device companies are located in the US.

Table 2: Top 10 Medical Device Companies 2018

Company	Revenue
1 – Medtronic, US	29.95 billion US$
2 – DePuy Synthes, Johnson & Johnson, US	26.6 billion US$
3 – Fresenius, DE	20.7 billion US$
4 – Philips Healthcare, NL	20.7 billion US$
5 – GE Healthcare, US	19.1 billion US$
6 – Siemens Healthineers, DE	16.5 billion US$
7 – Cardinal Health, US	13.5 billion US$
8 – Stryker, US	12.4 billion US$
9 – Becton Dickinson, US	12.1 billion US$
10 – Baxter, US	10.6 billion US$

1.1.7. Profile of the top three US medical technology companies

Medtronic (HQ Minneapolis, Minnesota)
Medtronic is an US-Irish medical technology company. After a 48 billion US$ merger with Covidien in 2015, Medtronic positioned itself as the dominant market leader for cardiovascular technology, services and solutions. Owning 22.6% of the market, their leading revenue segment encompasses the Cardiac and Vascular Group, followed by Minimally Invasive Therapies, Restorative Therapies, and the Diabetes Group.[26] Below is a comprised list of the sectors Medtronic services and what devices are in their product line. The revenue is based on their fiscal year in 2018.

[26] Source: Statista (2018), Distribution of Medtronic's revenue from 2014 to 2018, by segment (in million U.S. dollars), retrieved 14.01.2019

Sector	Devices	2018
Cardiac and Vascular	Aortic and Peripheral Vascular Cardiac Rhythm and Heart Failure Coronary and Structural Heart	11.4 billion US$
Minimally Invasive Therapies	Renal Care Solutions Respiratory, Gastrointestinal, and Informatics Surgical Innovations	8.7 billion US$
Restorative Therapies	Spine Brain Therapies Pain Therapies Specialty Therapies	7.7 billion US$
Diabetes	Advanced Insulin Management Multiple Daily Injection Solutions Non-Intensive Diabetes Therapies	2.1 billion US$

DePuy Synthes /Johnson & Johnson (HQ Warsaw, Indiana)
Johnson & Johnson's subsidiary company DePuy Synthes produces an array of medical devices and comes in second, after Medtronic, with 27 billion US$ in revenue. [27] They cover the sectors of orthopedic, cardiovascular, diabetes, vision care and surgery. Best selling products are in the fields of surgical vision, wound closure, bio-surgery, and electrophysiology. [28] Below is a comprised list of the sectors DePuy Synthes services and the devices they manufacture. The revenue is based on their fiscal year of 2018. [29]

Sector	Devices	2018
Diabetes	Diabetes Care Diagnostics Interventional Solutions	1 millions US$
Orthopedics	Hips Knees Trauma Spine & other	8.9 millions US$
Surgery	Advanced General Specialty	9.9 millions US$
Vision	Contact Lenses Surgical	4.6 millions US$

[27] Source: Hoovers (2018), Depuy Synthes, Inc., retrieved on 22.01.2019
[28] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[29] Source: Johnson & Johnson (2018), Reported Sales vs Prior Period ($MM), retrieved on 22.01.2019

Total Medical Devices		27 millions US$

General Electric Healthcare (HQ Milwaukee, Wisconsin)
GE Healthcare, headquartered in US in Fairfield, Connecticut, attributes its growth to emerging markets of South East Asia and Latin America. With a revenue of 18 billion US$ in 2017, their focus areas are 'Healthcare Systems' and imaging products, particularly mammography and CTS (computerized tomography). [30] Their areas of specialties comprise oncology, cardiology, and stroke. The revenue is based on their fiscal year in 2017. [31]

Sector	Devices	2017
Diagnostic imaging & services	Magnetic resonance Computed tomography Molecular imaging X-ray systems	8 billion US$
Mobile diagnostic & monitoring	Ultrasound Clinical Solutions Monitoring Mobile Health	4 billion US$
IT & digital Solutions	Enterprise Imaging Financial Management Care Area Workflows GE Health Cloud ™	2 billion US$
Life Sciences	Bio process Protein & Cell Sciences Contrast Media & Nuclear Tracers Cellular Therapy	4 billion US$

1.1.8. Key Distributors (Group Purchasing Organizations)

Table 3 shows the top GPOs in the US. GPOs maintain direct contact with hospitals, caregivers, and third-party service providers that require medical instruments. They strongly depend on their relationship with medtech companies and other vendors to serve their clients in the healthcare sector.

Table 3: Key Group Purchasing Organizations (GPOs)

[30] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019
[31] Source: GE (2018), GE Healthcare, retrieved on 22.01.2019

Company	Revenue
1- AmerisourceBergen	153 billion US$
2- Cardinal Health	136 billion US$
3- HealthTrust Purchasing Group	64 million US$
4- Henry Schein	12 billion US$
5- Intalere	44 million US$
6- McKesson Pharmaceutical	5.2 million US$
7- Premier Inc	1.6 billion US$
8- Provista	5.8 million US$
9- Vizient	1 billion US$
10 - MedAssets (Vizient)	529 million US$

1.1.9. Research and Development

The United States leads in the Research and Development of the medical technology industry. Expenditures for Research and Development (R&D) average a 7% of revenue. The medical device industry and many government institutions invest in R&D. A peak of R&D spending was reached in 2016 with an investment of 12.8 billion US$. The biggest spenders on R&D were Medtronic and Abbot Laboratories as shown in Table 4. It is expected that larger medtech companies will expand their R&D budget plan by approximately 3% by the year of 2020.

Table 4: Companies ranked by medical technology R&D spending worldwide in 2017 and 2024 (in million US dollars) [32]

Company	2017	2024
Medtronic (US)	2.253	2.738
Abbot Laboratories (US)	1.640	2.351
Philips (NL)	1.728	2.204
Johnson & Johnson (US)	1.610	2.024
Siemens (DE)	1.416	1.760
Roche (CH)	1.378	1.411
Boston Scientific (US)	974	1.381
Becton Dickinson (US)	774	1.365
Danaher (US)	939	1.293
Stryker (US)	787	1.152

The table above comprises the top 10 technology companies with the highest projected spending in 2024. The strongest European players are Philips followed by Siemens. US companies, nonetheless, remain the largest group of investors in the R&D medtech industry.

Research and development is a key element of health sciences. It defines the parameters and allows for future growth. With digital technology on the rise, and merging market sectors, international companies invest in acquiring small, innovative companies instead of in-house R&D. As in the opinion of Winthrop Turlows, it becomes easier and more cost effective to outsource operations and establish collaborations, rather than to cultivate new sectors. [33]

[32] Source: Statista (2017), Top 20 companies based on medical technology R&D spending worldwide in 2017 and 2014 (in million U.S. dollars), retrieved on 09.01.2019
[33] Interview with Winthrop Turlow, Executive Director of MedTech Association from 10.01.2019

1.2. Cardiovascular

1.2.1. Medical Technological Market for Cardiovascular Diseases

With cardiovascular disease (CVD) being the leading cause of death for men and women in the US, cardiology represents one of the largest sectors of the medtech industry in the US. According to the American Heart Association (AHA), 82.6 million people in the United States are affected by one or more forms of cardiovascular disease.[34] With the rising number of people being affected through diabetes, obesity, poor diet, and lack of physical activity, the cardiovascular sector is expected to grow annually.

1.2.1.1. Market Size & Growth

The cardiologist industry produced a revenue of 30 billion US$ and net earnings of 3.1 billion US$ in 2018 and is expected to grow at 5.7% by 2022 with an estimated sales volume of 62.3 billion US$.[35] The industry is in high demand for operators and currently provides employment to 86.000 employees.[36]

1.2.1.2. US companies for Cardiovascular[37]

The table below displays the biggest cardiovascular companies in the US market in alphabetical order.

Table 5: US companies for Cardiovascular

Companies	Key figures
Abiomed[38]	
Headquarters	Danvers, Massachusetts
Employees	1.100
Corporate Family	8 companies
Annual Sales	593 billion US$
Total Assets	887 million US$

[34] Source: National Academies Press (US), A Nationwide Framework for Surveillance of Cardiovascular and Chronic Lung Diseases, retrieved on 18.01.2019
[35] Source: Medtronic (2018), Facts and Statistics, retrieved on 14.01.2019
[36] Source: IBISWorld (2017), Cardiologists Industry in the US, retrieved on 14.01.2019
[37] Source: Statista (2017), Global top 10 companies based on cardiologic medical technology market share in 2017 and 2024, retrieved on 09.01.2019
[38] Source: Hoovers (2018), Abiomed, retrieved on 18.01.2019

Abbott Laboratories [39]	
Headquarters	North Chicago, Illinois
Employees	99.000
Corporate Family	768 companies
Annual Sales	27 billion US$
Total Assets	71 billion US$
Boston Scientific [40]	
Headquarters	Marlborough, Massachusetts
Employees	29.000
Corporate Family	266 companies
Annual Sales	9 billion US$
Total Assets	20 billion US$
Edwards Lifesciences [41]	
Headquarters	Irvine, California
Employees	12.000
Corporate Family	51 companies
Annual Sales	3.4 billion US$
Total Assets	5.9 billion US$
Getinge [42]	
Headquarters	Wayne, New Jersey
Employees	600
Corporate Family	214
Annual Sales	186 million US$
Total Assets	90 million US$
Johnson & Johnson [43]	
Headquarters	New Brunswick, New Jersey
Employees	134.000
Corporate Family	910 companies

[39] Source: Hoovers (2018), Abbott Laboratories, retrieved on 18.01.2019
[40] Source: Hoovers (2018), Boston Scientific, retrieved on 18.01.2019
[41] Source: Hoovers (2018), Edwards Lifesciences, retrieved on 18.01.2019
[42] Source: Hoovers (2018), Getinge, retrieved on 18.01.2019
[43] Source: Hoovers (2018), Johnson & Johnson, retrieved on 18.01.2019

Annual Sales Total Assets	76 billion US$ 155 billion US$
Medtronic [44] Headquarters Employees Corporate Family Annual Sales Total Assets	 Minneapolis, Minnesota 49.000 609 companies 19 billion US$ 55 billion US$
Terumo [45] Headquarters Employees Corporate Family Annual Sales Total Assets	 Somerset, New Jersey 3.4.000 177 companies 758 million US$ 288 million US$
W.L. Gore & Associates [46] Headquarters Employees Corporate Family Annual Sales Total Assets	 Newark, Delaware 9.800 78 companies 3.4 billion US$ N/A

[44] Source: Hoovers (2018), Medtronic, retrieved on 18.01.2019
[45] Source: Hoovers (2018), Terumo, retrieved on 18.01.2019
[46] Source: Hoovers (2018), W.L. Gore & Associates, retrieved on 18.01.2019

1.2.2. Associations for cardiovascular diseases

Shown in the table down below are prominent associations working in the field of cardiovascular disease.

Table 6: Associations for cardiovascular diseases

Associations	**Links**
American Heart Association	AHA
American College of Cardiology	ACC
Heart Rhythm Society	HRS
National Heart Foundation	NHF
World Heart Federation	WHF
US Department of Health and Human Services	HHS

1.3. Dentistry

1.3.1. Medical Technological Market for Dentistry

The US dental market is the largest globally. A special focus, due to Medicare, is being placed on oral health and greater insurance schemes that are more advantageous for potential patients. There is a rising demand for dental procedures in the field of restorative and surgical procedures. Those procedures are likely to create growth in the dental equipment market.[47]

1.3.1.1. Market Size & Growth

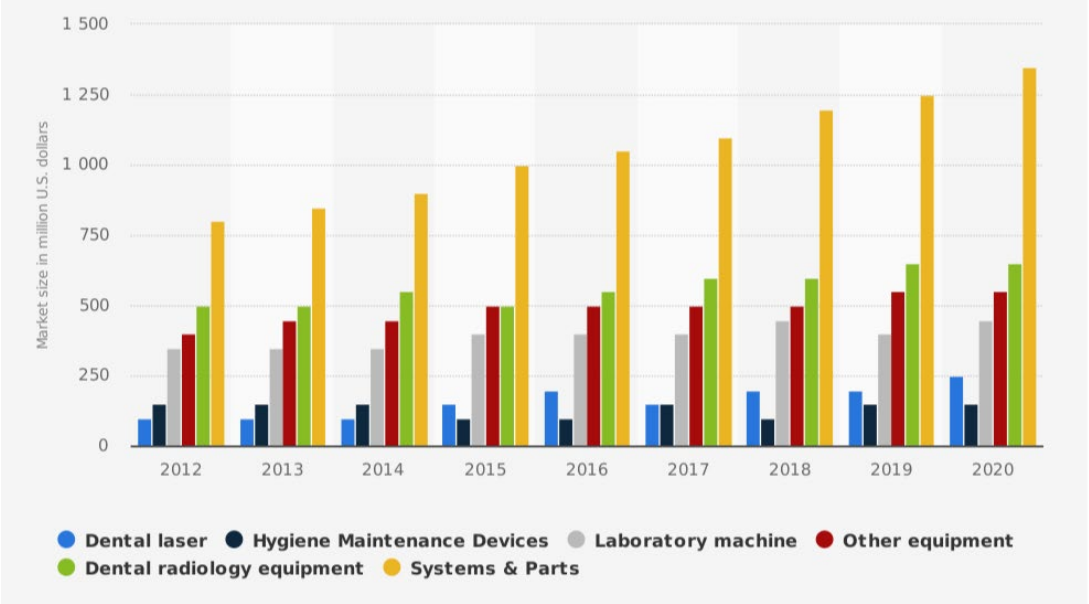
The total value of the dental equipment industry over the past five years has grown by 2.5% and is expetcted to produced a revenue of 135 billion US$ by 2019.[48] Due to the growing economic restoration and investment into healthcare the number of businesses has grown by 0.7% to 185.601. Due to aging population, an increased demand for cosmetic dentistry and an growing incidence of tooth decay, the market for dental equipment is expected to experience an annual growth of 2.1% to 131.7 billion US$.[49]

Over the past five years, the Dental Equipment Dealers industry has grown by 2.4% to reach revenue of 13 billion US$ in 2018. In the same timeframe, the number of businesses has grown by 1.5% and the number of employees has grown by 1.8%.

Figure 9 shows the expected growth of dental equipment in the fields of dental laser, hygiene maintenance devices, laboratory machine, dental radiology equipment, systems and parts, and other equipment by 2020.

[47] Source: IBISWorld (2018), Dental Equipment Dealers Industry in the US, retrieved on 14.01.2019
[48] Source: IBISWorld (2018), Dental Equipment Dealers Industry in the US, retrieved on 14.01.2019
[49] Source: IBISWorld (2018), Dental Equipment Dealers Industry in the US, retrieved on 14.01.2019

Figure 9: North America's dental equipment market size from 2012 to 2020 by product (in million US dollars)[50]



The service sector of dentistry in the US consists of dental consultation and diagnostic services, preventative services, restorative dental services, prosthodontics, orthodontics, surgical oral and maxillofacial services and nonsurgical endodontic services.

[50] Source: Statista (2016) , North America's dental equipment market size from 2012 to 2020, by product (in million U.S. dollars), retrieved on 17.01.2019

1.3.1.2. US companies for Dentistry

The table down below displays the major dentistry equipment manufacturers in the US market in an alphabetical order.

Table 7: US companies for Dentristry

Companies	Key figures
A-dec Inc. [51]	
Headquarters	Newberg, Oregon
Employees	1.900
Corporate Family	4 companies
Annual Sales	310 million US$
Total Assets	19 million US$
AMD Lasers [52]	
Headquarters	Indianapolis, Indiana
Employees	16
Corporate Family	N/A
Annual Sales	2.6 million US$
Total Assets	N/A
Biolase, Inc. [53]	
Headquarters	Irvine, California
Employees	195
Corporate Family	3 companies
Annual Sales	46 million US$
Total Assets	34 million US$
Carestream Health [54]	
Headquarters	Rochester, New York
Employees	7.000
Corporate Family	982 companies
Annual Sales	2 billion US$
Total Assets	N/A

[51] Source: Hoovers (2019), A-dec. retrieved on 14.01.2019
[52] Source: Hoovers (2019), AMD Lasers, retrieved on 14.01.2019
[53] Source: Hoovers (2019), Biolase, retrieved on 14.01.2019
[54] Source: Hoovers (2019), Carestream Health, retrieved on 14.01.2019

Danaher Corporation[55]	
Headquarters	Washington, DC
Employees	67.000
Corporate Family	646 companies
Annual Sales	18 billion US$
Total Assets	47 billion US$
Dentsply Sirona[56]	
Headquarters	York, Pennsylvania
Employees	16.000
Corporate Family	95 companies
Annual Sales	3.9 billion US$
Total Assets	8.7 billion US$
Henry Schein[57]	
Headquarters	Melville, New York
Employees	700
Corporate Family	354 Companies
Annual Sales	12 billion US$
Total Assets	7.8 billion US$
3M[58]	
Headquarters	Saint Paul, Minnesota
Employees	91.000
Corporate Family	656 companies
Annual Sales	31 billion US$
Total Assets	37 billion US$
Patterson Companies, Inc.[59]	
Headquarters	Saint Paul, Minnesota
Employees	7.700
Corporate Family	207 companies
Annual Sales	5.4 billion US$
Total Assets	1.2 billion US$

[55] Source: Hoovers (2019), Danaher Corporation, retrieved on 23.01.2019
[56] Source: Hoovers (2019), Dentsply Sirona, retrieved on 14.01.2019
[57] Source: Hoovers (2019), Henry Schein, retrieved on 23.01.2019
[58] Source: Hoovers (2019), 3M, retrieved on 14.01.2019
[59] Source: Hoovers (2019), Patterson Companies, Inc., retrieved on 14.01.2019

1.3.2. Associations for dental equipment

Shown in the table down below are prominent associations for dentistry.

Table 8: Associations for dental equipment

Associations	Links
American Dental Association	ADA
American Board of Pediatric Dentistry	ABPD
American Dental Education Association	ADEA
America's Pediatric Dentists	APD
Dental Trade Alliance	DTA

1.4. Oncology

1.4.1. Medical Technological Market for Oncology

The market for oncology is divided into segments and encompasses diagnosis and treating of cancer diseases with medical devices, in-vitro diagnostics and combination device products.[60] Early detection is vital. With the trend of big data mapping and new modalities in technological advancements, the market is expanding. Connectivity and internet-related devices, allow for better tracking. Endoscopic devices are projected to account for a major share because of the growing preference for these devices.[61] Screening of the infected site helps in early cancer detection. Especially the field of pharmaceuticals and research on cancer has been pushing the market growth of oncology in health sciences.[62]

It is estimated that 1.735.350 new cases of cancer would be diagnosed in 2018.[63] The most common cancer according to the National Cancer Institute are breast cancer, lung and bronchus cancer, prostate cancer, colon and rectum cancer, melanoma of the skin, bladder cancer, non-Hodgkin lymphoma, kidney and

[60] Source: FDA (2018), Oncology Devices and Diagnostics, retrieved on 18.01.2019
[61] Source: Statista (2018), Oncology, retrieved on 17.12.2018
[62] Source: Wiley Online Library (2018), Cancer Statistics 2018, retrieved on 23.01.2019
[63] Source: Transparency Market Research (2018), Oncology Devices Market, retrieved on 15.01.2019

renal pelvis cancer, endometrial cancer, leukemia, pancreatic cancer, thyroid cancer, and liver cancer.[64]

1.4.1.1. Market Size & Growth

National expenditures for cancer care in the United States in 2017 averaged at 147.3 billion US$. Costs are likely to rise in the coming years as the population ages and cancer prevalence increases. Moreover, costs are likely to rise as new, and often more expensive, treatments are adopted as standard of care.[65]

1.4.1.2. US companies for Oncology

The table below displays the major oncology equipment manufacturers in the US market in alphabetical order.

Table 9: US companies for Oncology

Companies	Key figures
Accuray [66]	
Headquarters	Sunnyvale, California
Employees	959
Corporate Family	15 companies
Annual Sales	404 million US$
Total Assets	369 million US$
Allogene Therapeutics [67]	
Headquarters	South San Francisco, California
Employees	78
Corporate Family	N/A
Annual Sales	1.7 million US$
Total Assets	148 million US$

[64] Source: National Cancer Institute (2018), Cancer State, retrieved on 18.01.2019
[65] Source: National Cancer Institute (2018), Cancer State, retrieved on 18.01.2019
[66] Source: Hoovers (2019), A-dec. retrieved on 14.01.2019
[67] Source: Hoovers (2019), Allogene Therapeutics, retrieved on 14.01.2019

C.R. Bard [68]	
Headquarters	New Providence, New Jersey
Employees	16.000
Corporate Family	384 companies
Annual Sales	3.7 billion US$
Total Assets	5.5 billion US$
Elekta[69]	
Headquarters	Atlanta, Georgia
Employees	100
Corporate Family	49 companies
Annual Sales	110 million US$
Total Assets	42 million US$
Flatiron Health[70]	
Headquarters	New York, New York
Employees	400
Corporate Family	470 companies
Annual Sales	1.2 billion US$
Total Assets	N/A
Guardant Health[71]	
Headquarters	Redwood City, California
Employees	348
Corporate Family	N/A
Annual Sales	49 million US$
Total Assets	362 million US$
Nanthealth[72]	
Headquarters	Culver City, California
Employees	864
Corporate Family	9 companies
Annual Sales	86 million US$
Total Assets	411 million US$

[68] Source: Hoovers (2019), C.R. Bard, retrieved on 14.01.2019
[69] Source: Hoovers (2019), Elekta, retrieved on 14.01.2019
[70] Source: Hoovers (2019), Flatiron Health, retrieved on 14.01.2019
[71] Source: Hoovers (2019), Guardant Health, retrieved on 18.01.2019
[72] Source: Hoovers (2019), Nanthealth, retrieved on 18.01.2019

Varian Medical Systems [73] Headquarters Employees Corporate Family Annual Sales Total Assets	 Palo Alto, California 6.600 72 companies 2.9 billion US$ 3.1 billion US$

1.4.2. Associations

Shown in the table down below are prominent associations for oncology. [74]

Table 10: Associations for oncology

Associations	**Links**
American Society of Clinical Oncology	ASCO
Community Oncology Alliance	COA
Society of Surgical Oncology	SSO
American Society for Radiation Oncology	ASTRO
American Society of Blood and Marrow Transplantation	ASBMT
American Association of Cancer Research	AACR
American Cancer Society	ACS
National Cancer Institute	NCI
National Comprehensive Cancer Network	NCCN

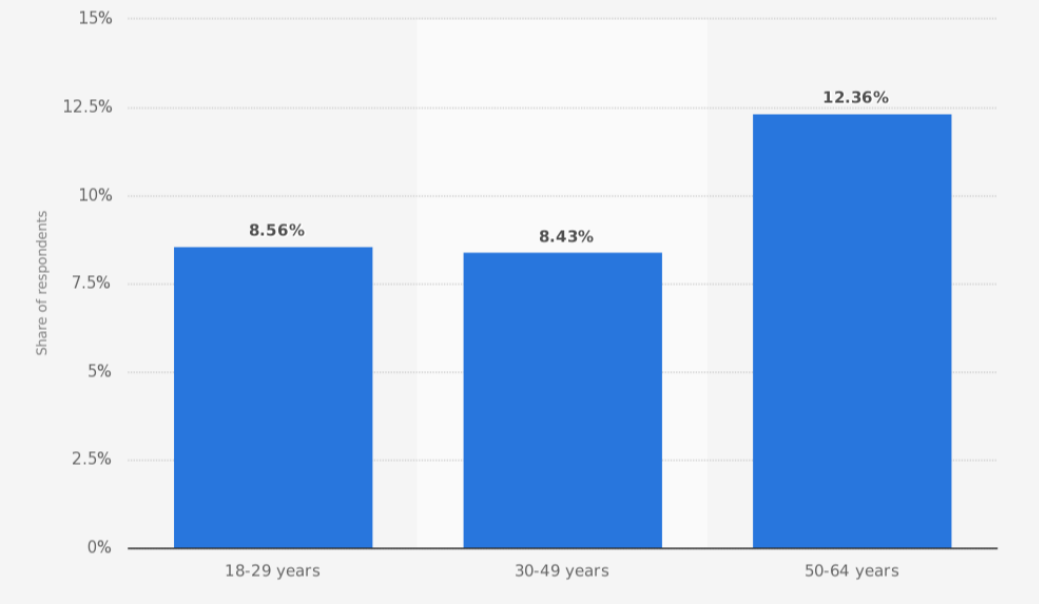
[73] Source: Hoovers (2019), Varian Medical Systems, retrieved on 18.01.2019
[74] APAO (2019), Oncology Professional Organizations, retrieved on 18.01.2019

1.5. Orthopedics

1.5.1. Medical Technological Market for Orthopedics

The orthopedic device market is expected to grow in the coming years. A special focus is laid on reducing diseases that come with old age as shown in Figure 10. The rise in osteoporosis, osteoarthritis, and musculoskeletal disorders due to old age is a driving factor for the orthopedic device industry. Orthopedics also covers the surge of surgery that deals with musculoskeletal system conditions such as trauma, sport injuries, degenerative diseases, infections, and tumors. Younger individuals in their 40s and 50s undertake orthopedic surgeries most commonly due to injuries and in need of orthopedic implants. The orthopedic sector is one of the fastest growing segments in the US medical device industry. The orthopedic implants and devices market forms a substantial part of the overall medical device industry and accounts for 125 billion US$ made in revenue.

Figure 10: Share of Americans who underwent orthopedic treatment in the last 3 years in 2018, by age[75]

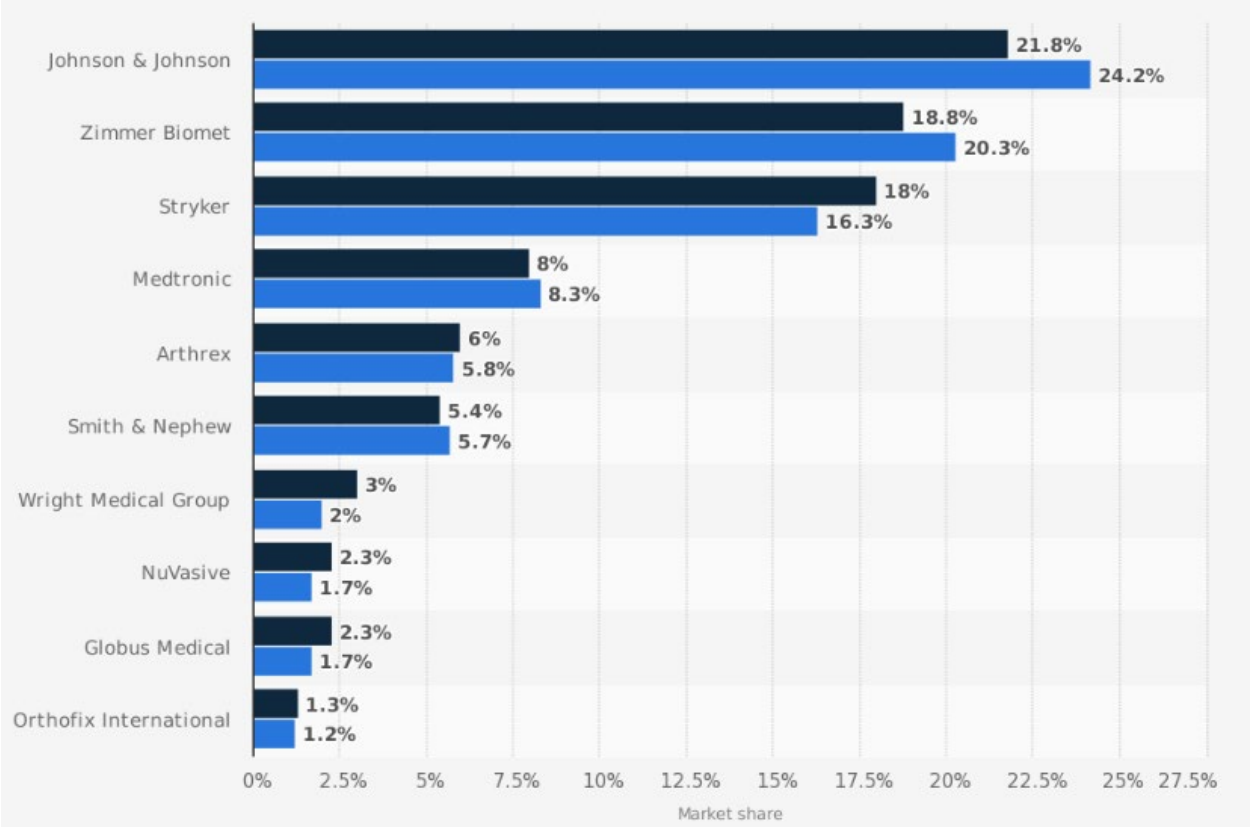


[75] Source: Statista (2018), Share of Americans who underwent orthopedic treatment in the last 3 years in 2018, by age, retrieved on 18.01.2019

1.5.1.1. Market Size & Growth

The US orthopedic device market was valued at over 20 billion US$ in 2016. The US orthopedic device market holds over 90% of regional revenue. It is projected to produce 25 billion US$ in revenue by 2024.[76] Traditional medical device companies display the biggest market share in the orthopedic sector.

Figure 11: Global top 10 companies based on orthopedic medical technology market share in 2017 and 2024.[77]



The top 10 leading medical companies for orthopedics, as shown in Figure 11, account for over 90 % of the market. However, the industry has reached a maturity stage, since the supply for orthopedics implants and devices has exceeded the demand.

[76] Source: Global Markets Insight (2017), Orthopedic Devices Market Size By Product, retrieved 18.01.2019
[77] Source: Statista (2018), Global top 10 companies based on orthopedic medical technology market share in 2017 and 2024, retrieved on 18.01.2019

1.5.1.2. US companies for Orthopedics

The table below displays the major manufacturers for orthopedics in the US market in alphabetical order.

Table 11: US companies for Orthopedics

Companies	Key figures
Arthrex[78]	
Headquarters	Naples, Florida
Employees	1.200
Corporate Family	28 companies
Annual Sales	426 million US$
Total Assets	1.3 million US$
Globus Medical[79]	
Headquarters	Audubon, Pennsylvania
Employees	1.400
Corporate Family	9 companies
Annual Sales	635 million US$
Total Assets	1.2 billion US$
Johnson & Johnson[80] (DePuy Products)	
Headquarters	Warsaw, Indiana
Employees	12.000
Corporate Family	941 companies
Annual Sales	1.3 billion US$
Total Assets	N/A
Medtronic[81]	
Headquarters	Minneapolis, Minnesota
Employees	49.000
Corporate Family	611 companies

[78] Source: Hoovers (2019), Arthrex, retrieved on 14.01.2019
[79] Source: Hoovers (2018), Globus Medical, Inc., retrieved on 18.01.2019
[80] Source: Hoovers (2018), Johnson & Johnson, retrieved on 18.01.2019
[81] Source: Hoovers (2018), Medtronic, retrieved on 18.01.2019

Annual Sales	19 billion US$
Total Assets	55 billion US$

NuVasive[82]	
Headquarters	San Diego, California
Employees	2.600
Corporate Family	19 companies
Annual Sales	1 billion US$
Total Assets	1.6 billion US$

Orthofix[83]	
Headquarters	Lewisville, Texas
Employees	525
Corporate Family	11 Companies
Annual Sales	122 million US$
Total Assets	N/A

Stryker Corporation[84]	
Headquarters	Portage, Michigan
Employees	33.000
Corporate Family	241 companies
Annual Sales	12 billion US$
Total Assets	22 billion US$

Wright Medical Group[85]	
Headquarters	Memphis, Tennessee
Employees	989
Corporate Family	55 companies
Annual Sales	298 million US$
Total Assets	1.1 billion US$

Zimmer Biomet Holdings[86]	
Headquarters	Warsaw, Indiana
Employees	18.000
Corporate Family	106 Companies

[82] Source: Hoovers (2018), NuVasive, retrieved on 18.01.2019
[83] Source: Hoovers (2018), Orthofix, retrieved on 18.01.2019
[84] Source: Hoovers (2018), Stryker Corporation, retrieved on 18.01.2019
[85] Source: Hoovers (2018), Wright Medical Group, retrieved on 18.01.2019
[86] Source: Hoovers (2018), Zimmer Biomet Holdings, retrieved on 18.01.2019

Annual Sales	7.8 billion US$
Total Assets	25 billion US

1.5.2. Associations for Orthopedic

Shown in the table down below are prominent associations for orthopedic.

Table 12: Associations for orthopedic

Associations	**Links**
American Academy of Orthotics and Prosthetics	AAOP
American Association for Surgery of Trauma	AAST
American Association of Hip and Knee Surgeons	AAHKS
American Association of Neurological Surgeons	AANS
American Association of Orthopaedic Executives	AAOE
American Association of Orthopaedic Surgeons	AAOS
American Association of Tissue Banks	AATB
American College of Surgeons	ACS
American Orthopaedic Association	AOA
American Orthopaedic Foot and Ankle Society	AOFAS
American Orthopaedic Society for Sports Medicine	AOSSM
American Shoulder and Elbow Surgeons	ASES
American Society for Surgery of the Hand	ASSH
American Society of Bone and Mineral Research	ASBMR
American Society of Orthopaedic Professionals	ASOP
American Spinal Injury Association	ASIA

American Sports Medicine Institute	ASMI

2. Regulatory affairs

2.1. US import regulation; general overview

All foreign items brought to the US have to meet the import requirements of the US Customs and Border Protection (CBP). Thus every item crossing the border is subject to customs clearance and duties (unless specifically exempted).
The US customs regulations are generally stated in section 19 of the US Code. Most of the specific regulations, however, are put down in section 19 of the Code of Federal Regulations (CFR - "Customs Duties"). Other responsible authorities besides the CBP are the US Immigration and Customs Enforcement (within the Department of Homeland Security, (DHS)), Department of the Treasury, United States International Trade Commission (ITC) and the International Trade Administration (ITA).[87]

2.1.1. Trade policy frame work

Besides being part of the World Trade Organization (WTO) the US has free trade agreements with many countries, notably USMCA, the United States-Mexico- Canada Agreement.[88] The WTO oversees most global trade in goods and services and provides arbitration in case of disputes. Free Trade Agreements lead to eased conditions, specifically elimination or progressive reduction of tariffs on qualified goods.[89]

2.1.2. Customs procedure

CBP does not require an importer to have a license or permit, but other agencies may require such documents or other certification, depending on the goods that are being imported.[90]
In most cases, customs business should be processed through a customs broker, acting on behalf of the importers needs. A valid customs broker license is mandatory.
Upon formal entry, the importer has to transmit an identification number to the authorities. In case of a resident importer (companies located in the U.S) this number is the IRS business registration number ("Internal Revenue Service employer identification number") or Social Security number. If the importer is a non-resident importer, CBP will assign an "Importer Identification Number" which will be valid for future customs business as well. Customs declaration in the US can only be made by the "Importer of Record" (IOR) meaning the owner, purchaser or customs broker.[91]

[87] Source: GTAI (2018), Merkblatt über gewerbliche Wareneinfuhren-USA, retrieved on 08.01.2019
[88] Source: USTR (2018), United Sates-Mexico-Canada Agreement, retrieved on 08.01.2019
[89] Source: GTAI (2018), Merkblatt über gewerbliche Wareneinfuhren und Basiswissen Einfuhr, retrieved on 08.01.2019
[90] Source: USgov (2018), Importing and Exporting, retrieved on 08.01.2019
[91] Source:GTAI (2018), Merkblatt über gewerbliche Wareneinfuhren – USA, retrieved on 10.01.2019

2.1.3. Import duties

Import duties are taxes paid for goods that are transported across international borders. In case of a trade agreement, however, some countries and goods are exempt from duties. These goods still have to be declared.
The customs tariffs are defined in the Harmonized Tariff Schedule of the United States (HTSUS) issued by the United States International Trade Commission. All goods that enter the United States are categorized according to the Harmonized Tariff Schedule. Besides those tariffs, certain products can be subject to additional duties.[92]
Example: Since July 2018, several products with origin from China are charged 25 percent of additional duties besides the basic customs duties.[93]

2.1.4. Import bans & restrictions

Prohibitions or restrictions apply to the import of certain goods into the US depending on various factors, e.g. the country of origin or product type.
Import restrictions limit the entry of certain products into the US An example of a category, which is limited by such restrictions, is medical devices.[94]
Manufacturers must be very cautious regarding country of origin requirements and potential for additional duties.
According to customs and international trade law expert Mariana del Rio Kostenwein, it is advisable to conduct an analysis of the country of origin of the device to ensure the products are e.g. not considered to be "Made in China" by CBP and subject to additional duties.[95]

2.1.5. Excurse: export restriction (EU)

Export control law restrictions may apply to goods, countries or persons for various reasons.[96]
The export of dual-use items is subject to control mainly carried out on the basis of European regulation (EC) No. 428/2009. Dual-use items are goods, software and technology that can be used for both civilian and military applications. The EU controls the export, transit and brokering of dual-use items, so the EU can contribute to international peace and security and prevent the proliferation of Weapons of Mass Destruction (WMD).[97] The relevant items are listed in Annex I of the regulation. Despite the fact that

[92] Source:CBP, Customs Duty Informatiom, retrieved on 08.01.2019
[93] Source: GTAI (2018), Merkblatt über gewerbliche Wareneinfuhren und Basiswissen Einfuhr, retrieved on 10.01.2019
[94] Source: GTAI (2018), Merkblatt über gewerbliche Wareneinfuhren und Basiswissen Einfuhr, retrieved on 10.01.2019
[95] Interview with Marina der Rio Kostenwein, Partner at Simon Gluck& Kane LLP, on 08.01.2019
[96] Source (2018): Zoll, Wirtschaft und Sicherheit, retrieved on 10.01.2018.
[97] Source : European Commission (2018), Dual-use trade controls, retrieved on 10.01.2019

medical devices may contain sensitive technology, they are not listed in the Annex or subject to control otherwise. In fact they are explicitly exempt according to the Annex.

2.2. Import of medical devices; specific regulations

Medical devices that are imported into the US must not only meet CBP requirements but also the regulations of the FDA. Products not meeting the FDA regulatory requirements may be detained upon entry, even if the product is authorized for marketing in another country.
Said requirements include the registration of establishment, listing of devices or premarket submissions among others.
At the beginning of the import process the importer or filer has to submit the necessary information to the local CBP office. The entry submission should contain the necessary information in order to identify the product (especially name of device & product code) and also contain the appropriate information demonstrating that the product is in compliance with FDA regulations. Upon entry into the U.S, FDA may examine certain devices to confirm all the requirements are being fulfilled. In this case there will be a notice given by FDA ("Notice of FDA Action").[98]

According to expert Mariana del Rio Kostenwein, the common legal issues European companies may face when first entering the US market include: determining whether or not the product is a medical device; in case of a medical device, determining the device classification; if required, preparing and submitting the necessary application to FDA for clearance and approval; determining device labelling as well as protecting the device's intellectual property. Ms. Del Rio Kostenwein also explained that although the Transatlantic Trade and Investment Partnership (TTIP) did not come into effect, the US and EU are discussing harmonization, which would make market entry easier for European medical device manufacturers.[99]

2.2.1. FDA's medical device regulation

Medical devices (radiation emitting or non-radiation emitting) or other products that emit radiation imported by foreign manufacturers also have to comply with applicable US regulations prior, during and after the import into the US or its territories. Those devices or products emitting radiation must meet FDA regulatory requirements in order to be imported. Regulatory approvals from other countries are not recognized by the FDA.[100]

[98] Source: FDA (2018), Importing into the U.S., retrieved on 10.01.2019
[99] Interview with Marina der Rio Kostenwein, Partner at Simon Gluck& Kane LLP, on 08.01.2019
[100] Source: FDA (2018), Importing into the U.S., retrieved on 10.01.2019

2.2.1.1. Statutory framework: FD&C Act, 21 CFR Parts 1-58, 800-1299; CDRH

There are several regulations which need to be observed when importing and introducing medical devices to the US market.

Federal Food, Drug, and Cosmetic Act (FD&C Act): This Act outlines the legal framework within which FDA operates. It allows regulating both medical devices (emitting radiation or not) and electronic radiation-emitting products. The FDA's level of control over these products is determined by this law, enabling them to develop, publish and implement regulations.[101]

Code of Federal Regulations (CFR): This codification contains the general and permanent rules. It represents the broad areas subject to the Federal Regulation. Most of the FDA's medical device and radiation-emitting product regulations are stated in Title 21 CFR Parts 800-1299. These regulations cover various aspects of design, clinical evaluation, manufacturing, packaging, labeling and post market surveillance of medical devices.[102]

Center for Devices and Radiological Health (CDRH): This institution is responsible for regulating companies who manufacture, repackage, relabel and/or import medical devices sold in the US It also sets the regulations regarding radiation-emitting electronic products (medical and non-medical).[103]

2.2.1.2. Regulated products

The FDA regulates medical devices in order to assure the safety and effectiveness of those devices. Additionally, it develops and carries out a national program (by the CDRH) in order to control unnecessary exposures to and assure safe use of ionizing and non-ionizing radiation-emitting electronic products.
In order to know whether a product will be regulated by FDA, it is necessary to determine whether the product is defined as a medical device according to section 201(h) or a radiation-emitting product, as defined in Section 531 of the FD&C Act or both. If the product meets these definitions, the FD&C Act applies, meaning the regulatory requirements set by the FDA have to be fulfilled.[104]

[101] Source: FDA (2018), What is the difference between the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA regulations, and FDA guidance?, retrieved on 17.01.2019
[102] Source: FDA (2018), Code of Federal Regulations (CFR), retrieved on 16.01.2019
[103] Source: FDA (2018), Overview of Device Regulation, retrieved on 16.01.2019
[104] Source: FDA (2018), Overview of Device Regulation, retrieved on 27.01.20189

Medical devices involved in the collection, processing, testing, screening, manufacture and administration of blood, blood components and human tissue and cellular products are, however, specifically regulated by the Center for Biologics Evaluation and Research (CBER).[105]

2.2.1.2.1. Medical device and radiation emitting device

Medical devices vary from simple bandages to complex programmable pacemakers with micro-chip technology and laser surgical devices. Furthermore, in vitro diagnostic products fall into this category, i.e. general-purpose lab equipment, reagents and test kits, which may include monoclonal antibody technology. In addition, certain electronic radiation emitting products with medical applications and claims can be defined as medical devices, such as diagnostic ultrasound products or x-ray machines.[106]

2.2.1.2.2. Medical device accessory

An accessory is a finished device intended to supplement, support or increase the performance of one or more parent devices. Parent devices in turn are finished devices whose performance is supplemented, supported or increased by one or more accessories. A device is considered an accessory if promotional material, labeling or other evidence of intended use show that the device is designed to supplement, support or extend another device.[107]
Example: An infusion pump system will usually include a stand and an infusion pump. The performance of the infusion pump is supported by the stand by allowing the infusion pump to hold medications and liquids in comfortable reach of the patient or caregiver and at a suitable height. In this example, the infusion pump would be considered the parent device and the stand would be considered the accessory to the infusion pump.

Articles that do not meet the definition of an accessory cannot be treated as such even though they may be used in connection with a device.
Example: A mobile smartphone would not be considered an accessory after having downloaded a medical app, since the smartphone was not specifically determined for use with the medical device.[108]

2.2.1.3. Control standards and tools – overview

General Controls are the basic rules of the Medical Device Amendments to the FD&C Act. These rules provide the FDA with the means of regulating devices to ensure their safety and effectiveness. They apply

[105] Source: FDA (2018), CBER Regulated Products, retrieved on 08.01.2019
[106] Source: FDA (2018), Products and Medical Procedures, retrieved on 08.01.2019
[107] Source: FDA (2018), Medical Device Accessories, retrieved on 09.01.2019
[108] Source: FDA (2018), Medical Device Accessories, retrieved on 09.01.2019

to all medical devices and include provisions relating to misbranding, device registration and listing, premarket notification, banned devices and notifications.

The Amendments established three regulatory classes for medical devices. The devices are classified according to the degree of difficulty in assuring their safety and effectiveness. Regulatory control increases from Class I to Class III.[109]
Class I (synonymous with General Control) is the least rigid of the three device classes provided in the Amendments. Placing a device in Class I, the FDA has to conclude that there is sufficient information available about the device. Devices in said Class are not subject to the restrictions of Class II or III. Moreover, those devices are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health.

The General Controls are applicable to all devices regardless of their classification. They are, however, the only level of controls that apply to Class I devices.[110]

2.2.1.3.1. Device classification (Class I, II, III)

As already mentioned, devices are classified according to the degree of difficulty in assuring their safety and effectiveness. In order to do so, the FDA has determined classifications for about 1,700 different generic types of devices and categorized them into 16 medical specialties, the so-called "panels" (e.g. cardiovascular devices).[111] Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control. Classification is therefore risk based, confirms expert Mariana del Rio Kostenwein. That is to say the risk the device poses to the patient or the user is a main factor in the assignment of the classification. Devices with the lowest risk are appointed to Class I while those with the greatest risk are appointed to Class III.

The three classes are the following:

1. Class I: General Controls
   - With Exemptions
   - Without Exemptions
2. Class II: General Controls and Special Controls
   - With Exemptions
   - Without Exemptions
3. Class III: General Controls and Premarket Approval (PMA)

[109] Source: FDA (2018), PMA Approvals, retrieved on 08.01.2019
[110] Source: FDA (2018), General Controls for Medical Devices, retrieved on 09.01.2019
[111] Source: FDA (2018), Device Classification Panels, retrieved on 08.01.2019

Among other criteria, the Class being assigned is decisive for the type of premarketing submission/ application required for FDA clearance to the market.

In case the device is classified as Class I or II (without an exemption) a 510(k) submission will be obligatory for marketing. If the device is classified as exempt it is subject to the limitations on exemptions. These limitations of device exemptions are covered under Section 21 CFR.
For Class III devices, a premarket approval application (PMA) is necessary unless the device is a preamendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMA's have not been called for. If so, a 510(k) submission is required. These Class III devices are therefore the most difficult devices to get approved by the FDA says expert Mariana del Rio Kostenwein. She further explained that the PMA process is more time consuming and costly than the requirements for Class II devices.[112]
The classification of a device is based on the intended use as well as the indication for use. These indications for use are usually taken from the device's labeling, but can also be stated orally during sale of the product. Example: A scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in the cornea".

In order to determine the device's appropriate classification, the regulation number is mandatory. This number can either be requested in the classification database or directly in the listing for the specific panel, confirms expert Mariana del Rio Kostenwein.[113]
Most medical devices can be classified by finding the matching description of the device in Title 21 CFR, Parts 862-892.[114]

2.2.1.3.2. Quality System (QS) regulation; CGMP & design controls

In order to ensure that the products meet the applicable requirements and specifications, the manufacturers have to establish and follow certain quality systems.
The quality systems for FDA-regulated products, such as medical devices are known as current good manufacturing practices (CGMPs). The respective CGMP requirements for devices are codified under 21 CFR part 820.[115]

[112] Interview with Marina der Rio Kostenwein, Partner at Simon Gluck& Kane LLP, on 08.01.2019
[113] Interview with Marina der Rio Kostenwein, Partner at Simon Gluck& Kane LLP, on 08.01.2019
[114] Source: FDA (2018), Classify Your Medical Device, retrieved on 10.01.2019
[115] Source: FDA (2018), Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, retrieved on 08.01.2019

The FDA has now revised these CGMPs and incorporated them into a quality system regulation (QS) in order to achieve consistency with quality systems worldwide and giving device manufacturers greater flexibility in managing quality requirements (61 FR 52602). The QS regulations include requirements regarding methods, facilities and controls used in the proof of designing, manufacturing, packaging, labeling, storing, installing and servicing of medical devices intended for human use.[116]

Since the QS regulations have to cover various types of devices, they only establish a framework, rather than specific rules for each product. This framework has to be followed by all manufacturers meaning they have to develop and follow procedures and fill in the details required to determine the current state-of-the-art manufacturing for the specific device.

These rules are applicable to finished device manufacturers who intend to commercially distribute medical devices. The definition of a finished device is found in 21 CFR 820.3(l) (any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled or sterilized).
Certain components such as blood tubing and diagnostic x-ray components are considered to be finished devices because they are accessories to finished devices. A manufacturer of accessories is subject to the QS regulation.
However, certain types of medical devices do not have to fulfill the CGMP requirements. These devices are exempted by FDA classification regulations (21 CFR 862 to 892).[117]

An important component of the QS regulations are design controls. They describe an interrelated set of practices and procedures that are incorporated into the design and development process. Design controls make systematic assessment of the design an integral part of development.[118]

2.2.1.3.3. Medical device reporting (MDR)

The Medical Device Reporting (MDR) regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers and device user facilities to report certain device-related adverse events and product

[116] Source: GovInfo (N.A.), Federal Register Volume 61, Issue 195 (October 7, 1996), retrieved 14.01.2019

[117] Source: FDA (2018), Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, retrieved on 08.01.2019.
[118] Source: FDA (1997), Design Control Guidance for Medical Device Manufacturers, retrieved on 08.01.2019

problems to the FDA.[119] It functions as a post-market surveillance tool in order to monitor device performance, detect potential device-related safety issues and contribute to benefit-risk assessments of these products. The goal is to detect and correct problems in a timely manner.[120]

Manufacturers: A report filed by the manufacturer is required when they learn that any of their devices may have caused or contributed to a death or serious injury (key terms are defined in 21 CFR 803.3.). Once the manufacturer becomes aware of the fact that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, a report has to be filed as well.

Importers: Importers are required to report to the FDA and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury. If an importer learns their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur, they are only required to notify the manufacturer.

Device User Facilities (i.e. hospital, ambulatory surgical facility): User facilities have to report a suspected medical device-related death to the FDA and the manufacturer. They also have to report a medical device-related serious injury to the manufacturer (or to the FDA if the medical device manufacturer is unknown). However, no report is needed in case of a device malfunction, but such incidents can be reported on a voluntary basis to the FDA.[121]

2.2.1.3.4. Label & Labeling requirements

The general labeling requirements for medical devices are stated in 21 CFR Part 801. These regulations specify the minimum requirements for all devices. Additional regulations can be found in Parts 809, 812, 820, 830.[122]
Labeling in this context means providing proper information about name and place of the business, the intended use of the device as well as adequate directions for use, meaning a directive for safe use.
A device is considered misbranded if it makes a false or misleading statement with respect to another device, drug, food or cosmetic.
Exemptions may be granted due to lack of sufficient space for the required labeling if labelling space is not depleted by including non-required information. The existing label space may not be used for any

[119] Source: FDA (2018), Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities, retrieved on 08.01.2019
[120] Source: FDA (2018), Medical Device Reporting (MDR), retrieved on 10.01.2019
[121] Source: FDA (2018), Medical Device Reporting (MDR), retrieved on 10.01.2019
[122] Source: FDA (2018), General Device Labeling Requirements, retrieved on 08.01.2019

representations in a foreign language. All labeling shall be in English with the exception of products distributed solely within Puerto Rico or a US territory where the predominant language is other than English.
If any representation on the device label or labeling appears in a foreign language, then all required labeling shall also appear in that foreign language.[123]

Other relevant regulations are stated in the FD&C Act, specifically in Section 201(k) and Section 201(m).[124]

2.2.1.4. Premarket Submission

After having classified a device, there are several different premarket submissions depending on the applicable regulation. The following are the most common types of premarket submissions.[125]
The FDA has developed several types of resources to assist with a premarket submission. For more information please visit the FDA's website.[126]

2.2.1.4.1. 513(g) Application

The 513(g) submissions provide aid clarifying the FDA's view about the classification and the regulatory requirements that may be applicable to a device. A submission therefore constitutes a request for information. In order to receive all the necessary information, the submission should outline the characteristics of the device. The FDA will evaluate the information within 60 days and issue a ruling on how the device should be classified.[127]
For more details visit the FDA 513(g) guidance document.[128]

2.2.1.4.2. 510(k) submission – Premarket notification

Most Class II but also some Class I devices require a 510(k) submission. This notification requires the manufacturer to demonstrate that the new device is "substantially equivalent" to a predicate device in terms of intended use, technological characteristics and performance testing.[129]
The notification has to be sent to the FDA at least 90 days in advance for review, confirms expert Mariana del Rio Kostenwein. This way, the FDA is able to determine whether the device is equivalent to a device already placed into one of the three classification categories, and "new"

[123] Source: FDA (2018), General Device Labeling Requirements, retrieved on 08.01.2019
[124] Source: FDA (2018), Device Labeling, retrieved on 10.08.2019
[125] Source: FDA (2018), How to Study and Market Your Device, retrieved on 17.01.2019
[126] Source: FDA (2018), Device Advice: Comprehensive Regulatory Assistance, retrieved on 08.01.2019
[127] Source: FDA (2018), Guidance for Industry and Food and Drug Administration Staff, retrieved on 18.01.2019
[128] Source: FDA (2018), Guidance for Industry and Food and Drug Administration Staff, retrieved on 18.01.2019
[129] Source: FDA (2018), How to Study and Market Your Device, retrieved on 07.01.2019

unclassified devices can be properly identified. In case a medical device manufacturer intends to introduce a device into commercial distribution for the first time or reintroduce a significantly modified device (affecting safety and effectiveness), are required to submit a premarket notification.[130]

For additional information visit the FDA's Device Advice Premarket Notification 510(k).[131]

2.2.1.4.3. Premarket approval (PMA)

PMA poses the most stringent type of premarket submission (application under section 515). It is used to evaluate the safety and effectiveness of only Class III medical devices. A premarket approval (PMA) is the FDA's process of scientific and regulatory review.
Because of the high level risk associated with Class III devices, general and special controls are not sufficient to assure safety and effectiveness of these devices.
Some Class III preamendment devices may require a Class III 510(k) submission.
The applicant has to receive FDA approval of their PMA application prior to marketing the device. An approved PMA is a private license granting the applicant permission to market the device.
According to FDA regulations, the review timeframe for PMAs is 180 days, though in most cases the period is longer, says expert Mariana del Kostenwein.[132]

2.2.1.4.4. De Novo classification

The De Novo process provides a means for classifying a new device without a valid predicate but already providing reasonable assurance of safety and effectiveness for the intended use through general and or special controls.
De Novo classification is a risk-based classification process. Devices being classified into Class I or II through this process may be marketed and also used as predicated for future premarket notifications, 510(k) submissions.[133]

2.2.1.4.5. Humanitarian Device Exemption (HDE)

For a device to be eligible for an HDE, a sponsor has to obtain designation as a Humanitarian Use Device (HUD). A HUD describes a

[130] Source: FDA (2018), 510(k) Clearances, retrieved on 10.01.2019
[131] Source: FDA (2018), Premarket Notification 510(k), retrieved on 08.01.2019
[132] Source: FDA (2018), Premarket Approval (PMA) , retrieved on 09.01.2019

[133] Source: FDA (2018), Evaluation of Automatic Class III Designation (De Novo), retrieved on 08.01.2019

medical device intended to benefit patients in the treatment or diagnosis of rare diseases.
HDE in turn describes a marketing application for an HUD. It states an exemption from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.[134]

2.2.1.4.6. Investigational Device Exemption (IDE) for clinical studies

An investigational device exemption (IDE) allows for an investigational device to be used in a clinical study in order to collect safety and effectiveness data. Clinical studies are mostly conducted to support a Premarket Approval. In terms of 510(k) submission there are only few requiring clinical data to support the application.
Investigational use includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.
All clinical evaluations of investigational devices require an approved IDE before the study is initiated.
Following an approved IDE, a device can be shipped lawfully for the purpose of its conducting investigations without fulfilling other requirements of the FD&C Act which would usually apply with devices in commercial distribution. Accordingly, there is no need to submit a PMA or 510(k) and also no registration of the establishment or the device.[135]

2.2.1.5. Registration and Listing

An annual registration with the FDA is required for all establishments involved in commercial distribution within the US, including those distributions imported for export only. According to Title 21 CFR Part 807 most of said establishments are also required to list the devices as well as the activities performed on those devices at the establishment. Based on the different types of activities performed, the requirements for registration vary. Moreover, different requirements apply for domestic and foreign establishments.
For more details, visit the FDA's website.[136]

2.2.1.5.1. Establishment registration (initial, annual)

The obligation to register applies to all establishments. This includes all owners or operators of places of business, thus allowing the FDA to obtain the location of the establishment. By knowing where devices are made, the US is better able to prepare for and respond to public health emergencies.[137] All device establishments need to complete their annual

[134] Source: FDA (2018), Humanitarian Device Exemption, retrieved on 08.01.2019
[135] Source: FDA (2018), Device Advice: Investigational Device Exemption (IDE), retrieved on 08.01.2019
[136] Source: FDA (2018), Who Must Register, List and Pay the Fee, retrieved on 08.01.2019
[137] Source: FDA (2018), Device Registration and Listing, retrieved on 08.01.2019

registration for each fiscal year between October 1st and December 31st.[138]

2.2.1.5.2. Medical device listing

Besides the requirement to register most of the establishments are also expected to list the devices manufactured at the establishment as well as the activities performed on them. In case a certain device requires premarket approval before being marketed in the U.S, the owner or operator should provide the FDA with a premarket submission number. Both registration and listing must be submitted electronically with an own account using the FDA's unified system and listing module. [139]

2.2.1.5.3. Fees

The FDA will collect an annual establishment registration fee for device establishments. Payment must be made in order to register the establishment.[140] For 2019 the fee amounts to $4,884.[141]

2.2.2. Supplementing & displaced regulations

Besides the FDA, there are other agencies, on a federal and state level, regulating the market entry of medical devices. Accordingly, there can be some jurisdictional overlap between the FDA and other agencies in terms of some aspects or components of a medical device.

2.2.2.1. Federal level (FCC, CPSC, OSHA)

Federal Communications Commission (FCC):
The purpose of the FCC is to oversee the use of the public Radio Frequency (RF) spectrum within which RF wireless technologies operate. RF wireless medical devices perform at least one function that utilizes wireless RF communication such as Wi-Fi or Bluetooth to support health care delivery.
Example: controlling and programming a medical device or monitoring patients remotely.[142]
The FDA's policies on wireless medical devices are coordinated with the FCC and provide medical device manufacturers with more predictability and a better understanding of regulatory requirements for medical devices that utilize these technologies.[143] In fact there is a Memorandum of Understanding in which the agencies agree to work together to

[138] Source: FDA (2018), Important Reminders about Registration and Listing, retrieved on 09.01.2019
[139] Source: FDA (2018), Device Registration and Listing, retrieved on 09.01.2019
[140] Source: FDA (2018), Payment Process, retrieved on 09.01.2019
[141] Source: FDA (2018), Device Registration and Listing, retrieved on 09.01.2019
[142] Source: FDA (2018), Wireless Medical Devices, retrieved on 08.01.2019
[143] Source: FDA (2018), Wireless Medical Devices, retrieved on 08.01.2019.

promote a health information technology (IT) framework that promotes innovation, protects patient safety and avoids regulatory duplication.[144]

Consumer Product Safety Commission (CPSC):
The responsibility of the CPSC is to protect the public from unreasonable risks of injury associated with consumer products. In order to accomplish said task the Commission is authorized, among other things, to issue consumer product safety standards or to establish requirements for warnings and instructions. In that regard the commission has jurisdiction over many types of consumer products. However, some types of consumer products are covered by other Federal agencies, depending on the particular class of "consumer product". A Memorandum of Understanding delineates the respective areas of jurisdiction between the two agencies.[145]In terms of jurisdiction of medical devices, the FDA has the sole jurisdiction.[146]

Occupational Safety and Health Administration of the Department of Labor (OSHA):
OSHA is required to enforce the Occupational Safety and Health Act of 1970 (OSH Act), under which employers are responsible for providing safe and healthful workplaces for their employees. Its role is therefore to assure these conditions by setting and enforcing standards, and providing training, education and assistance.[147]
The requirements of the FDA to obtain market clearance for medical devices are unrelated to these OSHA requirements. OSHA's jurisdiction concerns protecting the employees (physicians, nurses, medical technicians) who use the device. The jurisdiction of the FDA on the other hand concerns testing the safety and efficacy of medical devices with regard to the manner in which these devices are used (i.e., medical safety of patients).Typically, the FDA evaluates the extent to which the devices meet the purported treatment objectives in a manner that does not endanger the patient, while OSHA is responsible for ensuring that the equipment is safe for use by employees in the workplace.
Moreover, the FDA regulates the manufacturers of medical devices, while OSHA regulates the employers. [148]
However, there is a Memorandum of Understanding between the two agencies in order to share relevant information while ensuring that the exchange of such information complies with applicable law.[149]

[144] Source: FDA (2018), MOU 225-14-0002, retrieved on 08.01.2019
[145] Source: FDA (2018), MOU 225-14-0002, retrieved on 08.01.2019
[146] Source:CPSC (2018), Products Under the Jurisdiction of Other Federal Agencies and Federal Links, retrieved on 08.01.2019
[147] Source: OSHA (2018), The Occupational Safety and Health Administration, retrieved on 08.01.2019
[148] Source: OSHA (2018), 1910 Subpart S, retrieved on 08.01.2019
[149] Source: OSHA (2018), The Occupational Safety and Health Administration, retrieved on 08.01.2019

2.2.2.2. State level

While most of the time manufacturers focus their regulatory resources on compliance with federal requirements by the FDA, a significant portion of device regulation falls within the purview of state agencies, particularly with respect to device distribution.
In terms of device distribution, regulations are set by the state Board of Pharmacy or Board of Wholesale Distributors. Some states utilize an FDA-like agency, while others have multiple agencies that share the responsibilities in this area.[150]

2.3. Medical device reimbursement

Reimbursement and payment are key factors in determining sales growth and market adoption. Medical communication, reimbursement, and continued compliance with regulatory requirements are particularly essential for a successful sale and distribution of medical devices.

With regard to device manufacturers that obtain reimbursement for their product, consideration must be given to the Sunshine Act.[151]

2.3.1. Sunshine Act

The Sunshine Act requires manufacturers of drugs, medical devices and biologicals participating in U.S federal health care programs to track and then report certain payments and items of value (gifts) given to physicians and teaching hospitals. Those parties are defined as "Covered Recipients". Physicians, in terms of the Sunshine Act, are any of the following types of professionals who are legally authorized to practice: Doctor of Medicine, Doctor of Osteopathy, Doctor of Dentistry and Doctor of Dental Surgery.
The report has to be sent to the Centers for Medicare and Medicaid Services (CMS) on a yearly basis. The data is then published annually in a publicly searchable database.[152]

Financial relationships between physicians and medical product manufacturers are common and are often a key component in the development of new drugs and devices. While these relationships can have positive aspects to it, they also do create conflicts of interests and can even blur the line between promotional activities and the conduct of medical research, training, and practice.[153]

[150] Source: MorganLewis (2015), State Regulation of Medical Device Distribution Update, retrieved on 09.01.2019
[151] Source: NAMSA (N.A.), Planning for Successful Medical Device Reimbursement, retrieved on 10.01.2019
[152] Source: Celgene (2018), Sunshine Act FAQ, retrieved on 09.01.2019
[153] Source: Health Affairs (2014), The Physician Payments Sunshine Act, retrieved on 08.01.2019

Examples are the cost of meals provided to physicians, payments made to Covered Recipients in exchange for services provided, such as advisory boards, speaker programs and consulting engagements. Travel and provision of reprints of medical journal articles to Covered Recipients are also subject to the Act.[154]

Companies in the research and development phase for devices not approved or cleared by the FDA may not be subject to the Sunshine Act.[155]

Regarding a value limitation, a report is only required if an individual physician receives a single payment in excess of $10 or exceeds $100 in payments per year from an individual manufacturer.[156]

However, payments or individual gifts are not prohibited. The purpose of the Act is to identify inappropriate behavior by tracking the payments and also making them accessible to the public. Furthermore, the Act does not replace state disclosure and transparency laws. So far, there is no analysis whether the Act has resulted in a reduction of financial influence of manufacturers over healthcare providers, says expert Mariana del Rio Kostenwein.[157]

2.3.2. Coverage, Coding and Payment

Coverage, Coding and Payment are the tree pillars of reimbursement and each one stands alone.[158]

Coverage: Coverage refers to a payor's decision to provide program benefits for a specific product or service. This coverage is usually conditional on FDA clearance, the product not being deemed experimental or investigational, the medical necessity of the product, and the appropriateness of the product's use for the patient in the treatment setting.[159]
Coverage via National Coverage Decision (NCD) or a Local Coverage Decision only applies to new medical procedures and technologies that are not currently defined in the regulations. An NCD applies only to a fraction of new devices and requires significant amount of clinical data.
The different emphasis placed on approvals by the FDA and the requirements for reimbursement by insurance companies poses a change to companies. Insurance requirements typically follow CMS guidelines. The FDA stresses safety and efficiency while the CMS focuses on superiority of a product as a main criterion. This difference makes it challenging to achieve both clearance

[154] Source: Celgene (2018), Sunshine Act FAQ, retrieved on 09.01.2019
[155] Source: NAMSA (N.A.), Planning for Successful Medical Device Reimbursement, retrieved on 10.01.2019
[156] Source:Rx Vanatage, https://www.rxvantage.com/sunshine-act/.
[157] Interview with Marina der Rio Kostenwein, Partner at Simon Gluck& Kane LLP, on 08.01.2019
[158] Source: NAMSA (N.A.), Planning for Successful Medical Device Reimbursement, retrieved on 10.01.2019
[159] Source: The Atticus Group (2018), Understanding Reimbursement for Medical Devices: Coding, Coverage, Payment and Payors, retrieved on 10.01.2019

and coverage, with the FDA making decisions on a predicate device and CMS looking for novelty.[160]

Coding: Coding translates into payment, making it the link between coverage and payment. A proper code is necessary in order for procedures and products being paid for. The type of code varies. There are numerous of types depending on where and by whom the procedure is being performed as well as the equipment involved. Coding is often the focus of reimbursement analysis for cleared products.[161]

Payment: The amount a hospital or physician practice will get paid for a certain product determines sales; it is the reward for all effort that it took to get the product approved.
Many devices are used as part of inpatient or outpatient procedures that are covered by a single payment to the hospital for a procedure. Hospital systems are expected to provide their services at a lower cost while improving quality. Companies can often create a value proposition for direct purchase of devices that reduces length of stay, readmission and procedure time.[162]

2.3.3. Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare and Medicaid Services (CMS) provide health coverage through Medicare, Medicaid, Children's Health Insurance Program and the Health Insurance Marketplace.[163]
For a medical device manufacturer, it is essential to achieve CMS coverage in order demonstrate clinical and economic value for reimbursement. Medicare coverage decisions are made through CMS's National Coverage Determination (NCD) process. This program is intended to ensure prompt and efficient patient access to safe, effective and appropriate medical devices for the Medicare population.[164]

CMS (as well as private payors, hospitals, phiysicians, etc.) expect data to be presented in the form of journal publications in order to review the new medical device. The publication of data should be planned early in the product development process.
A relationship between physicains and medical device companies is of high importance but also creates additional regulatory considerations once a device

[160] Source: NAMSA (N.A.), Planning for Successful Medical Device Reimbursement, retrieved on 10.01.2019
[161] Source: NAMSA (N.A.), Planning for Successful Medical Device Reimbursement, retrieved on 10.01.2019
[162] Source: NAMSA (N.A.), Planning for Successful Medical Device Reimbursement, retrieved on 10.01.2019
[163] Source: USgov (2018), Centers for Medicare and Medicaid Services, retrieved on 08.01.2019
[164] Source: Policy & Medicine (2018), Medical Device Parallel Review Program Made Permanent, retrieved on 09.01.2019

is cleared for sale. Within the medical community the device needs to be accepted in order to drive sales. The best way to achieve such acceptance is by having the product presented at medical society meetings.[165]

[165] Source: NAMSA (N.A.), Planning for Successful Medical Device Reimbursement, retrieved on 10.01.2019

3. Market access

3.1. Market opportunities for foreign companies in the US-MedTech Industry

The continuous globalization of the US-MedTech industry is projected to surge in the future, providing promising market opportunities for foreign companies.

The industry performed well over the past five years considering the industries high-margin, strong competition and the fact that it produced mainly non-discretionary products. However, revenue decreased at the beginning of last year due to small profit margins of hospitals, which limited the ability to raise capital for large purchases. Revenue in 2018 was forecasted with a growth of 2.7% to 39.5 billion US$. Industry growth is supported by an aging population, the expansion of healthcare coverage and technological progress. Furthermore, economic prosperity has also stimulated more consumers to seek medical care, leading to increased spending on healthcare with an annual growth rate of 3.5% over the past five years.

Compared to previous generations, baby boomers in general have a higher interest in taking care of their own healthcare due to better finances, education and wellness engagement. They are also interested in patient focused, in-home care for diabetes, heart disease and other chronic conditions. Advances in technology are expected to meet the demand of home medical devices, with the ability to quickly and easily connect to a healthcare provider´s electronic records.

Drivers, such as healthcare reform, technological progress, outsourcing, regulations and the aging population, which have pushed the industry over the past five years, are expected to continue. The collective outcome of these various factors is expected to boost revenue growth at a rate of 3.0% annually to a total of 45.8 billion US$ in 2023. Additionally, the change in US demographics is also in favor of the industry.

It is expected that small and medium sized companies are will target niche markets with the focus on one or two medical devices. Thus, the number of players in the industry is anticipated to rise over the next years to 2023.

According to IBISWorld[166] the following key success factors are the most important for businesses in this industry:

[166] Source: IBISWorld (2018), Medical Device Manufacturing in the US Industry Report, retrieved on 16.01.2019

- **Access to highly skilled workforce**

Due to the fact that the design and production of medical devices is highly technical, companies and organizations with access to skilled staff have a competitive advantage. The significance of a skilled workforce can be reflected in the industry' s high average wage.

- **Access to the latest technology**

It is also very important that companies have access to the latest technology. This can be accomplished by investing in R&D or the acquisition of other enterprises that hold patented technologies.

- **Establishment of export markets**

Another key to success for a company is to operate globally. Therefore, it is important to also focus on a global expansion to develop export markets and not to solely rely on the domestic market.

- **Economies of scale**

Companies that operate large manufacturing facilities also should reduce variable costs and sales prices while monitoring to profit margins.

- **Having contacts within key markets**

It is also important to have access to distributors and end users in order to successfully sell products.

Although US companies have a tendency to dominate the industry, the expansion of international giants shows that industry profits are generated more through global outreach efforts, especially in China, Japan and Europe.

The medtech industry consists of a substantial number of foreign players that operate subsidiaries and facilities in the US. The industry is also consolidating and reaching out to emerging markets for sales. One example is the acquisition of Covidien by Medtronic in 2015.

3.2. Market barriers

Companies are often not in the position to lead in price negotiations due to big purchasing groups that act as distributors for about half of the hospitals in the US (see chapter 1.1.8. Key Distributors). Most of the larger manufacturers trust purchasing groups with the distribution of their products. Therefore, small and medium sized medical device and supply companies are excluded from sales to hospitals since the bigger players often secure exclusive contracts with purchasing groups. [167]

[167] Source: IBISWorld, Medical Device Manufacturing in the US, Medical Device Manufacturing in the US Industry Report, retrieved on 18.01.2019

The high average profit margins of the medical device manufacturing industry may increase the interest of potential industry participants, but there are several market entry barriers that should be considered and that may hinder industry entry. These include heavy regulation, high investment costs, large competition and the fast pace of technological progress. Most products of this industry are manufactured under patents. As a result, companies are very protective of their technological expertise and intellectual property. Industry operators who are trying to enter certain industry markets may experience demanding technical requirements with limited access to technical information. Thus, companies that are interested in competing in specialized products probably have to invest a significant amount of resources in research and development.

An additional market entry barrier may come with certain government policies. In the US medical devices are regulated by the Federal Food Drug & Cosmetic Act. Every company is required to comply with their regulations regarding medical devices. This control mechanism is the baseline requirement which applies to all devices that are needed for marketing, proper labeling and monitoring. (see chapter 2. Regulatory affairs).[168]

Barriers to market entry checklist:

Competition	High
Concentration	High
Life Cycle Stage	Growth
Capital Intensity	Low
Technology Change	High
Regulation & Policy	Heavy
Industry Assistance	Medium

Source: IBISWorld, Medical Device Manufacturing in the US

Additionally, fees for insurances to protect against product liability claims may also discourage market entry. Especially in the field of healthcare, claims could result in prohibitively high costs with an upward trend. Another barrier is represented by the access to a very skilled labor force in order to perform high-level R&D. Very skilled and specialized labor is limited in this industry.[169]

In general, it can be stated that the barriers to entry of the US MedTech industry are medium and steady, although it is often necessary to adapt products to the market, due to differences in needs and expectations between consumers from different cultures. This not only affects the products themselves, but also marketing strategies.

[168] Source: IBISWorld, Medical Device Manufacturing in the US, Medical Device Manufacturing in the US Industry Report, retrieved on 18.01.2019
[169] Source: IBISWorld, Medical Device Manufacturing in the US, Medical Device Manufacturing in the US Industry Report, retrieved on 18.01.2019

Often European entrepreneurs are more interested in technical details and tend to analyze all contingencies and possibilities before making a decision. Americans are principally more pragmatic and make decisions more instinctively. In general, it can be stated that facts are more important for European entrepreneurs, whereas their American counterparts find the presentation of the products more important.

Apart from the cultural aspects, the US also differs in terms of contract and liability law, as well as technical standards compared to Europe. In addition, legal regulations and standards may differ among the 50 US states. Companies planning to become active in the American market should obtain comprehensive information on regional and national legal and technical regulations, in order to minimize liability and recourse risks in advance. Furthermore, individual and consumer protections are much more significant in the US as opposed to in Europe.

3.3. Sales structure and market entry strategies

There are various strategic opportunities for foreign companies to start and sustain sales activities in the US. The two most common types are distribution through sales representatives and direct sales with own employees. Regardless of the chosen distribution strategy, the objectives and roles of all parties should be clearly defined when entering into a contract. Also relevant is the potential US customer.

After analyzing the market and deriving an appropriate entry strategy, it is important to address the second milestone – how to build business contacts - unless it has already been done in parallel to market research and analysis. In this phase, personal contacts are often crucial. It is recommended that these contacts be linked, constructed and/or expanded via local trade fairs and/or event participation. The appearance of a European company at trade fairs or other events also conveys a genuine interest in the US market and the search for business partners.

According to AHK USA's experience, it is imperative for foreign companies to have a presence (virtually or physically on site) in the American market in order to make market entry and expansion more effective.

It is also very important to tailor and adapt the marketing concept to the needs of the US market. This includes e.g. the communication of the "Value Added Proposition" or the unique selling points of the product or service in meaningful information material. For European products and services, the advantages over comparable American products or services should be clear. The focus should be on the customer benefit (e.g., health benefit, time or cost savings), not on the procedure or technical details. Furthermore, it should be considered that the marketing effort in the US can sometimes be more intense, requiring a larger marketing budget than in the domestic market.

3.3.1. Sales Channels

3.3.1.1. Direct Sales

Although direct selling is often the best strategy for long-term success, local distributors can drive market entry in addition to the sales representatives of their own company. Because of the size and diversity of the country, direct selling and distribution through partners can often be combined to cover different regions of the US. Basically, there are several types of distribution partners in the US, including sales agents and distributors. In principle, it should be noted that direct and indirect sales in the US are not mutually exclusive. It must be individually reviewed which strategy a company wants to utilize in the long term. Very often, the US is divided into different sales regions, which are indirectly supported by the company and partly by the local partners.

3.3.1.2. Sales Representative & Distributor

The "Sales Representative" in the USA, places orders for a commission but does not have the authority to conclude contracts on his own. Thus, the sale of the goods takes place in the name and for the account of the European company. If the commercial agent succeeds, their contracts usually are resolvable at short notice thus minimizing business risk. As part of this distribution model, however, the entire responsibility for transport, service, repair, collection and product liability usually rests with European company. A sales representative often serves a specific geographic region that can span from one city to several states. In the case of an offer intended to cover large-area territories within the USA, it is advisable to check in advance whether the agency can map a sufficient network in the entire target region and indeed has suitable contacts with the desired clientele. Basically, the cost of a sales representative is lower than that of own personnel in the US market. Some sales representatives charge a monthly fee for their services, called "Territory Development Fees" or "Retained Service Fees". However, since most of the US is commission-based, products with long sales cycles are rarely sold successfully by sales representatives.

In contrast to sales representatives, distributors directly buy the products and goods and then sell them under their own name. As a result, the distributor also assumes the risks of selling and is additionally responsible for the service after the sale of the product. Distributors can facilitate the sale and, in particular, the service for products in different regions. Especially in a large country like the US, it is necessary to

provide service in different states and regions. An advantage of working with distributors is that the business risks (except product liability and intellectual property) are with the distributor. The distributor has an interest in promoting the sale and usually has an appropriate distribution network. The disadvantage is that customers are often unknown to the European company. Also, the risk exists that additionally competing products are distributed within the same portfolio.

3.3.1.3. Group Purchasing Organizations for hospitals (GPOs)

Group Purchasing Organizations are playing are large role in the medtech industry. GPOs are organizations which have the task to assist healthcare providers to help to safe costs and to become more efficient. This is done by combining purchasing power in order to negotiate discounts with industry operators that provide healthcare, e.g. manufacturers, distributors and other healthcare companies. In the US approximately 96-98% of the hospitals belong to at least one GPO, whereas a typical hospital will use two GPOs amongst the 600 GPOs US-wide. It can be said, that about 72 percent of the hospital purchases in the US are carried out by using GPO contracts with approximately 10 to 15 percent cost saving by using a GPO.[170]

One of the reasons why GPOs have become more dominant is the shift from private practices to large hospitals. GPOs acting as the institution's administration take a larger role in the purchasing decision. This change in the buying decision of devices from physicians to administrators has shifted the focus to cost and value considered purchasing. Additionally, reimbursement usually favors larger-tier medical device manufacturers. GPOs are able to take advantage of value propositions and product differentiation towards bigger, more cost-conservative buying organizations and insurers. As a result, GPOs have replaced private practices as the main the decision makers in the procurement of medical devices, which creates a barrier for smaller manufacturers and continues to prioritize value based, as well as bigger medical device companies. The following trends can be observed:

- Larger manufacturers acquiring smaller competitors to expand market share
- Hospitals undergoing corporate realignments, hindering entrance of smaller manufacturers
- Increased focus on cost-savings in hospitals
- Pricing pressures from GPOs, Medicare and other large private payers
- Higher focus on reimbursement and pricing for smaller manufacturers earlier in product development cycles

[170] Source: Business Sweden (N.A.), The U.S. Medical Device Inudustry, retrieved on 16.01.2018

The process of selling to GPOs can be competitive and time consuming, especially when the bidding and review process is lengthy and can take from three months up to a year. Usually, GPOs use a bid calendar that outlines the purchase cycles and shows which product category will be procured. The determined parameter that GPOs utilize is similar to the ones that are important to hospital executives, which are high quality at the lowest possible cost (high value for money). In addition, the vendor's distribution infrastructure will be examined to make sure that high volume purchase orders can be handled properly. Lastly, vendor financials and quality services, as well as field support, are being looked at as well.

There are several steps that should be followed if a company considers selling to GPOs. The first step should be the vendor's registration with a selected GPO. The GPOs will publish a bid calendar outlining the procurement plan throughout the year which allows vendors to plan when they should approach GPOs. Business opportunities are offered by the GPOs through Request-for-Proposals (RFP) which will be forwarded to registered suppliers. After receipt of all proposals, the GPO starts to analyze each proposal and further negotiates contracts with vendors before a contract will be awarded.[171]

The following steps should be considered when selling to GPOs:

- Supplier registration
- GPO issues bid calendar for procurement categories
- Supplier registers for RFP or GPO issues RFP to list of applicable registered suppliers
- GPO analyzes proposals and products
- Negotiations between suppliers and GPOs
- GPO awards contract

Further information on GPOs can be found on the website of Healthcare Supply Chain Association (HSCA)[172]

3.3.2. Presence in the USA

It is particularly important to show local presence in the USA. Due to the potential language barrier and time difference, it can be considered an obstacle if a European company does not have a local address and phone number in the US. Customer service is very important in the US and therefore needs to be done locally in the local language. As soon as a US market presence in the form of a subsidary or even in the form of an address and telephone number (virtual

[171] Source: Business Sweden (N.A.), The U.S. Medical Device Inudustry, retrieved on 16.01.2018
[172] Source: Healthcare Supply Chain Association (HSCA), group purchasing organization (GPO), retrieved on 18.01.2019

office / "business presence") is present, the sales opportunities for foreign companies often increase significantly.

It is also important to note that although the US is a country, there are 50 states with different state and local regulations. It is therefore highly recommended - especially at the beginning of market entry - to choose a region and then, as soon as the company is consolidated in the regional market, to expand further. For the selection of the region in which to start, it is recommended to carry out a detailed market research on supply and demand as well as the involved stakeholders etc.

In addition, the topic of personnel allocation should already be on the agenda at the beginning. Cultural differences show that Europeans tend to do very detailed planning, calculations etc. This speaks for the quality of European products, but is not effective for a marketing strategy in the US. It is therefore advisable to seek a mix of US-Americans and own nationals in the search for personnel.

However, for a foreign company with substantial activities in the US it is advisable and necessary to set up a presence in the US. Determining the way of setting up such presence depends on many different aspects within the business.

In general, there are two main options: 1) Virtual or 2) Physical office. Both types are sufficient to run a branch office or as headquarter for an US - subsidiary.

A virtual office is a virtual office environment with the benefits of an US business address. For example, the virtual office services offered by the GACC New York include establishing a company's personalized mailing address and phone line in Manhattan's Financial District at an affordable price. Specially trained, bilingual employees in our consulting department manage incoming and outgoing correspondence and answer calls on behalf of the company. However, there are numerous other service providers in the US that offer a similar service, e.g. Regus[173] or Servcorp[174].

The main question is, however, whether to form a branch or a subsidiary when considering opening a presence. The liabilities and financial impacts vary significant. Whereas a branch exposes the company's entire earnings, an incorporated subsidiary limits this kind of financial exposure.[175]
Moreover, companies need to take into account that a US company corporation is administered at the state level (state law, federal law only being applicable occasionally); therefore, the process does differ from state to state.[176]

[173] Source: Regus
[174] Source: Servcorp
[175] Source: GACC brochure „Firmengruendung in den USA"
[176] Source: GACC brochure „Firmengruendung in den USA"

3. 3. 2. 1. Branch

A branch office does not constitute a separate legal entity of the parent company, but is an unincorporated extension of a foreign parent company operating a sales office or other income producing activity in the US.[177] However, due to this structure the parent company is fully exposed to any and all business risk inherent in doing business in the US. This option is therefore not chosen very often.[178]

3. 3. 2. 2. Subsidiary / US Legal Entity

A subsidiary is a separate legal entity from the parent company, but still owned by the parent company. It can be formed as any type of legal entity; the most common forms are corporations and limited liability companies.[179] Most foreign companies choose to set up a corporation since it can be established quickly, only requiring minimal administrative burden. Furthermore, it allows a centralized management as well as limitation of liability.[180]

There are mainly four types of companies in the United States: General Corporation (C Corporation), S Corporation, Close Corporation, Limited Liability Company (LLC). Each form has advantages and disadvantages in complexity, ease of setup, cost, liability protection, periodic reporting requirements, operating complexity, and taxation.

A General Corporation (or "C Corporation") is the most common corporate structure for medium and large companies. An S Corporation is actually a C Corporation which then obtains a special tax status from the Internal Revenue Service (IRS). Both C and S Corporations offer limited liability protection. Both require articles of incorporation to be filed. And both comprise shareholders, directors, and officers. There are lots of similarities, but they differ in the complex realm of taxation and corporate ownership.

C corporations are subject to double taxation while S corporations are pass-through tax entities, allowing them to avoid being taxed at the corporate level and again on shareholders' personal income taxes. C corporations have no restriction on ownership, S corporations are restricted to no more than 100 shareholders who must be US citizens or residents.

A Close Corporation is similar to a C Corporation, except the number of shareholders is limited to 30, the transfer of shares is conditional to the

[177] Source: US Branch Office
[178] Source: US Branch Office
[179] Source: US Branch Office
[180] Source: GACC brochure „Firmengruendung in den USA"

directors' prior approval and the prohibition to trade shares on the stock exchange.

A Limited Liability Company (LLC) is formed by one or more individuals or entities through a special written agreement. Unlike an S corporation or C corporation, the structure of an LLC is flexible. The LLC business structure combines the pass-through taxation of a partnership or sole proprietorship with the limited liability of a corporation.

In order to set up a business in the US, following steps should be considered:

1. Choosing which type of business entity to form: Corporation or LLC

   If any of the company owners (called "Shareholders" for corporations and "Members" for LLC's) are not US Citizens, then either a Corporation or an LLC can be formed.

2. Choosing in which state to form the Corporation or LLC

   In the United States, you can form a Corporation or LLC in any of the 50 States. Some US-States are more "business-friendly" or "international-friendly" than others (e.g. Delaware).

3. Designating a registered agent

   The Registered Agent has a statutory responsibility to accept official state documents and legal documents and forward them to the company.

4. Providing names and addresses of the people/companies involved (Officers, directors, members, etc.)

5. Acquiring an EIN

   The Federal Employer Identification Number (FEIN) also known as an "EIN" or simply "Tax ID Number" is a number issued by the United States Internal Revenue Service (IRS) that is somewhat like an identification number for companies. It allows you to open bank accounts, pay taxes and hire employees.

The German American Chamber of Commerce, Inc. can provide support in setting up a legal entity in the United States.[181]

[181] Source: GACC brochure „Firmengruendung in den USA"

Having a permanent, incorporated subsidiary in the US has several benefits: The parent company will be protected from potential liabilities in the US Additionally it will simplify bookkeeping and accounting, making tax compliance less costly and more efficient, being able to cover insurance and to open a bank account. The subsidiary can also be qualified as a local company when bidding on certain contracts.[182]

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[182] Source: GTAI (2018), Unternehmensgründung und Gewerbeanmeldung in USA, retrieved on 08.01.2019

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