# **Medical Devices**

# **Health Care Sector**

#### Investment Thesis

We recommend an overweight rating for the medical devices industry, driven by strong secular growth, rising demand from an aging population, and increasing AI integration. The post-pandemic recovery in elective procedures and advances in robotic-assisted surgery and remote monitoring create new revenue opportunities. Despite regulatory and pricing pressures, companies that maintain diversified portfolios and strongly invest in R&D are best positioned for long-term growth.

#### **Drivers of Thesis**

The medical devices industry is well-positioned to benefit from technological advancements, particularly through the integration of AI, which is being used to enhance diagnostic capabilities, personalize treatment, and streamline manufacturing, ultimately improving product performance and reducing costs.

- An aging global population, supported by longer life expectancy, is driving sustained demand for advanced medical devices to improve healthcare outcomes.
- The rise of telemedicine and remote patient monitoring is shifting demand toward connected and home-based medical devices, expanding revenue opportunities by enabling more continuous and accessible healthcare delivery.

#### **Risks to Thesis**

- Al integration in medical devices may prove ineffective or too costly, diminishing expected benefits and delaying widespread adoption.
- Policy uncertainty under the new administration, including potential tariffs and trade restrictions, could disrupt supply chains and increase costs for medical device manufacturers.
- Stricter FDA and global regulatory standards may lead to approval delays, higher compliance costs, and slower product innovation cycles.

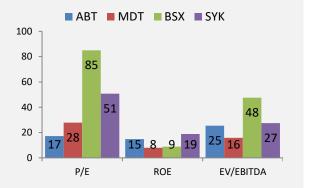


# HenryFund.Org

# February 12, 2025

**OVERWEIGHT** 

Key Industry Metrics					
Market Cap (\$B)					
Medtronic (MDT)	\$115.4				
Boston Scientific Corp. (BSX)	\$155.1				
Stryker (SYK)	\$149.2				
Abbott Laboratories (ABT)	\$223.9				
P/E (NTM)					
Medtronic (MDT)	15.4x				
Boston Scientific Corp. (BSX)	36.9x				
Stryker (SYK)	28.9x				
Abbott Laboratories (ABT)	25.1x				
EV/EBITDA					
Medtronic (MDT)	15.9x				
Boston Scientific (BSX)	47.6x				
Stryker (SYK)	27.4x				
Abbott Laboratories (ABT)	25.4x				
ROE (TTM)					
Medtronic (MDT)	7.9%				
Boston Scientific (BSX)	8.9%				
Stryker (SYK)	18.9%				
Abbott Laboratories (ABT)	14.8%				



#### Industry Description

The Medical Devices industry encompasses a wide array of products essential for patient care, diagnosis, and treatment. This includes devices, instruments, apparatuses, and consumables utilized by healthcare professionals and patients. The range of products spans from simple tools like syringes and bandages to advanced technologies such as imaging systems and surgical instruments. Key segments within the industry include diagnostic devices, therapeutic devices, monitoring equipment, and consumables. The industry is poised for continued growth, driven by increasing demand for healthcare services, advancements in medical technology, and the growing adoption of minimally invasive and personalized treatments.

Important disclosures appear on the last page of this report.



# **INDUSTRY OVERVIEW**

The Medical Devices industry is a vital segment of the healthcare system, providing essential tools and technologies that enable medical professionals to deliver effective patient care. During the COVID-19 pandemic, the demand for accurate diagnostic devices surged as healthcare providers needed solutions to control the virus's spread. Industry players responded quickly, developing key diagnostic technologies that became indispensable during the crisis. However, as the pandemic recedes, the industry has shifted its focus to long-term growth, maintaining a positive outlook for the future.

One of the major disruptions caused by the pandemic was the decline in healthcare visits, particularly for elective procedures. Medical device manufacturers are now anticipating a return to pre-pandemic levels of patient visits, especially for postponed surgeries and treatments. Many procedures were delayed indefinitely, creating a significant backlog that the industry expects to drive demand for surgical equipment and related medical devices in the coming years. For instance, companies like Teleflex have increased their annual profit forecasts due to continued strong demand for surgical procedures, particularly those delayed during the COVID-19 pandemic.<sup>1</sup>

Beyond the post-pandemic recovery, the Medical Devices industry faces new challenges and opportunities. One key development is the rise of GLP-1 weight loss drugs. While these medications have raised concerns about their potential impact on medical device utilization, particularly in areas like bariatric surgery, sales of diabetes-related medical technologies remain strong. This suggests a complementary relationship between these medications and the industry's core products. Another area that could be affected by the rise of GLP-1s is the volume of knee and hip replacement procedures. These surgeries are often required by obese individuals whose excess weight places added stress on their joints. If GLP-1s continue to prove effective for weight loss, the demand for such procedures may decline. However, this potential reduction might not significantly impact medical device companies if, as previously mentioned, they expect revenue from weightrelated drugs and devices to outpace the loss from fewer joint replacements. The impact of GLP-1s is likely to be more nuanced, with some companies and segments affected more than others.<sup>2</sup>



From a long-term perspective, demographic shifts will play a pivotal role in shaping demand. Advancements in medical technology have extended human life expectancy, increasing the proportion of elderly individuals within the global population. As aging populations grow, the demand for medical devices, surgical instruments, and advanced treatment solutions will follow. The industry anticipates sustained growth, driven by the need for continuous innovation to meet the evolving healthcare demands of an aging society.

Below are the top 10 largest players within the Medical Devices industry, by market capitalization:

Company (Ticker)	Market Cap (\$B)	Total Sales (\$M) (2024)	Net Income (\$M) (2024)
Abbott Laboratories (ABT)	\$227.2	\$41,950	\$13,351
Intuitive Surgical (ISRG)	\$172.9	\$8,352	\$2,323
Boston Scientific (BSX)	\$140.6	\$16,747	\$1,854
Stryker Corporation (SYK)	\$132.2	\$22,595	\$2,993
Medtronic (MDT)	\$105.9	\$32,364	\$3,676
Becton Dickinson (BDX)	\$57.1	\$20,178	\$1,705
Alcon (ALC)	\$45.8	\$8,728	\$897
Edwards Lifesciences (EW)	\$41.9	\$5,440	\$1,401
ResMed (RMD)	\$31.2	\$4,685	\$1,021
DexCom (DXCM)	\$26.8	\$4,033	\$576

Source: FactSet as of 4/19/25

# Revenue

The Medical Devices industry has seen strong revenue growth driven by technological advancements, increased healthcare demand, and the growing need for innovative healthcare solutions.

In 2024, U.S. medical device manufacturing generated \$54.7 billion in revenue.<sup>4</sup>

Medical Device Manufacturing in the US **Revenue** 

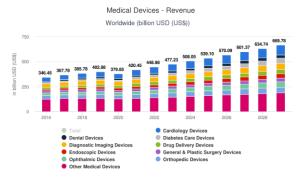
Total value (\$) and annual change from 2012 – 2030. Includes 5-year outlook



Source: IBISWorld

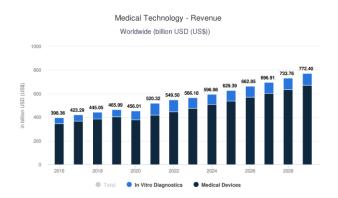
Globally, the industry reported \$596.9 billion in revenue for the year.  $^{\rm 5}$ 





Source: Statista

Medical devices represent the largest segment of the broader medical technology industry. A key distinction is that in vitro diagnostics (IVD) focus specifically on medical tests conducted on body samples, whereas medical devices encompass a wider range of technologies for diagnosis, treatment, and monitoring.



Source: Statista

Medical devices possess a crucial role in the healthcare space by providing innovative technological solutions that improve patient care, medical procedures, and overall efficiency of the healthcare system. Overall, we expect strong growth within the industry and are looking for companies that are ready to take advantage of the arising possibilities.

# MARKET DYNAMICS

# **Key Drivers**

# **Research & Development**

The healthcare sector places a strong emphasis on research and development (R&D) to drive innovation and improve patient care. By investing in R&D, companies can enhance the effectiveness and efficiency of their products,



ensuring they meet evolving medical needs and industry standards.



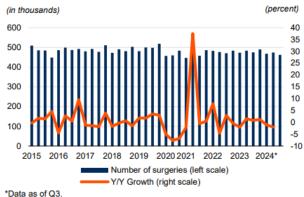
Source: CFRA Research, S&P Global Market Intelligence

R&D spending as a percentage of revenue has grown in recent years as companies focus on developing innovative technologies like continuous glucose monitors (CGMs) and surgical robotics. Strong R&D margins have supported this trend, and spending is expected to continue rising, driven by the increasing prevalence of chronic diseases, an aging population, and the demand for more efficient and effective healthcare solutions.

# Same Facility/Hospital Surgeries

A key metric in the healthcare sector and medical devices industry is the growth or change in same-facility surgeries. This refers to surgical procedures performed at the same hospital or healthcare facility where the patient was initially evaluated, admitted, or diagnosed. Tracking this metric provides valuable insight into surgical volume trends, facility utilization, and overall demand for surgical services.

Below is a figure showing the trend in same-facility surgeries from 2015-2024:



Source: CFRA Research, Company Reports

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Hospitals remain a key consumer of medical devices and supplies, with surgical volumes reaching 1.92 billion procedures in 2023, reflecting a 0.34% increase from the 1.91 billion recorded in 2022. However, CFRA projections indicate a 1.5% year-over-year decline in same-facility surgeries by 2025, likely driven by advancements in non-invasive treatments and a growing shift toward outpatient care.<sup>6</sup>

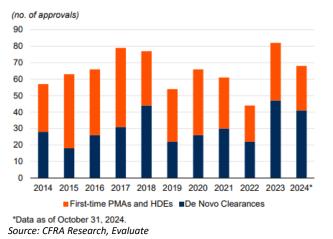
This creates a notable dynamic in the healthcare sector, where, while medical devices remain essential for certain procedures, technological advancements are increasingly shifting the focus toward non-invasive alternatives. For example, non-invasive coronary CT angiography has reduced the need for more invasive procedures like coronary angioplasty in some cases, highlighting this shift in treatment approaches.<sup>7</sup>

#### **New Device Approvals**

The process of new device approvals is closely linked to R&D in the medical devices industry. Healthcare is heavily regulated to ensure patient safety, quality, and ethical standards, among other factors. As a result, companies developing medical devices must adhere to stringent standards to ensure their products meet these regulatory requirements.

The approval process is a critical aspect of the medical devices industry and presents a significant hurdle for companies. The process varies depending on the device's classification and associated risks. A more detailed discussion of this process will be provided in a later section of this report.

Below is a figure showing the number of FDA approvals, and their type, from 2014-2024:





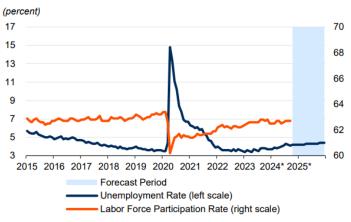
Despite challenges from the pandemic and regulatory oversight by the FDA, new device approvals rose significantly in 2023, with 82 approvals compared to 44 in 2022. While a higher number of approvals is generally positive for the industry, it can also raise concerns if driven by relaxed safety standards, potentially leading to device recalls and lawsuits. As of October 31, 2024, 68 new devices had already been approved.<sup>8</sup>

## **Unemployment Rate**

The unemployment rate has a significant impact on the healthcare industry, which in turn affects the medical devices sector. Unemployed individuals typically have limited access to quality healthcare, which in turn influences the utilization of medical devices.

In addition, the labor market directly affects the medical devices industry by impacting workforce availability. A rise in unemployment can lead to a shortage of skilled workers, hindering companies' ability to design, manufacture, and distribute medical devices. Furthermore, this shortage can disrupt the supply chain, reducing the industry's capacity to meet demand. Lastly, reduced access to healthcare due to unemployment may lead to delays or avoidance of necessary treatments, ultimately decreasing the demand for medical devices.

Below is a visual representation of the unemployment rate from 2015 to 2025 (projected), highlighting recent trends and ongoing challenges in labor force participation, particularly in engaging a larger portion of the population despite job creation:



\*Actual data through September 2024, forecasted unemployment data by Action Economics in shaded area.

Source: CFRA Research, U.S. Bureau of Labor Statistics, Action Economics

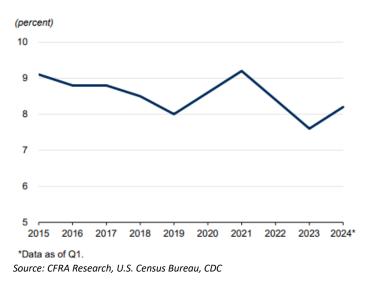


The Henry Fund forecasts the unemployment rate to remain at around 4.20% in the next 2 years. This means that we believe the impact of the unemployment rate on the medical devices industry should remain minimal. However, this can obviously be challenged by an unexpected occurrence such as something similar to the COVID pandemic, which we see caused a drastic increase in the unemployment rate mirrored by a decrease in the labor force. With that being said, the unemployment rate is an important metric to keep an eye out for as it could provide essential insight as to how the industry will perform or react to certain changes in the metric.

# **Uninsured Rate**

The uninsured rate has a significant impact on the medical devices industry through its effect on healthcare access. At the most basic level, if individuals are not insured, they are less likely to receive necessary or recommended procedures. This, in turn, leads to a decrease in demand for these procedures, and subsequently, a reduction in demand for the medical devices required for them.

Below is a figure showing the uninsured rate from 2015-2024:



The medical devices industry has seen benefits from the decline in the number of uninsured Americans over recent years. The percentage of people with health insurance rose to 92.4% in 2023, up from 89.6% in 2014, with the majority holding private insurance (69.1%).<sup>9</sup>

However, we expect a short-term rising unemployment rate to contribute to an increase in the uninsured rate in 2025. Additionally, potential policies from the Trump



administration aimed at reducing Medicaid enrollment could further increase the number of uninsured individuals. We are uncertain, but wouldn't be surprised if the new administration started to roll back historical policies such as the Affordable Care Act that was implemented during the Obama presidency. Trump poses to be a wild card where there is uncertainty as to what he is doing and the reasoning behind it. As a result, the uncertainty surrounding the new administration and its impact on healthcare coverage is an important factor to monitor.

# Challenges

# **Regulatory Compliance & Approval**

One of the primary challenges in the medical devices industry is navigating complex regulatory compliance and approval processes. Companies must adhere to stringent regulatory frameworks, such as the U.S. Food and Drug Administration (FDA) approval process, which can be lengthy, costly, and uncertain. While these regulations are essential for ensuring patient safety and maintaining industry standards, delays in approval can significantly impact product timelines and revenue for manufacturers.<sup>10</sup>

# **Product Recalls & Liability Risks**

Patient safety is a critical concern in the healthcare industry, making product recalls and liability risks a major challenge for medical device manufacturers. Defective or unsafe medical devices can lead to costly recalls, legal liabilities, and reputational damage. Companies must invest heavily in quality control and risk management systems to mitigate these risks and ensure compliance with safety standards.<sup>11</sup>

An example that depicts the magnitude of certain product recalls can be highlighted by the recent Abiomed Impella Heart Pumps recall in 2023. Abiomed is a Johnson & Johnson subsidiary which recalled 66,000 Impella leftsided heart pumps after receiving reports that the devices caused left ventricular wall perforation (a serious complication where a hole forms in the wall of the left ventricle of the heart). The FDA classified this recall as the most serious type, a Class I recall, as 49 deaths and 129 injuries were reported. This resulted in serious litigation against Abiomed claiming design and manufacturing defects, failure to warn, and negligence. The lawsuits are



ongoing but this emphasizes the risks and importance of compliance with safety standards.

# **Technological Advancements & Innovation**

Innovation and technological advancements are key drivers of growth in the medical devices industry, but they also present challenges. Companies must continuously develop new technologies while maintaining high safety and functionality standards. Balancing innovation with regulatory compliance and cost considerations creates a highly competitive environment, where firms must differentiate themselves while ensuring product quality and market viability.<sup>12</sup>

#### **Global Market Dynamics**

Expanding into global markets introduces additional complexities, including increased competition and varying regulatory requirements across regions. Managing international operations, navigating trade barriers, and adapting to diverse healthcare systems pose significant challenges for companies pursuing global expansion. Successfully addressing these factors is crucial for sustaining growth and maintaining a competitive edge in the industry.<sup>13</sup>

# **Opportunities**

The medical devices industry is always changing and developing as newer technologies and innovations become available, along with new opportunities. Below are some of the key opportunities presented within the industry.

## Integration of Artificial Intelligence (AI)

Al is becoming increasingly prevalent across industries, driving technological advancements and expanding its capabilities. The medical devices industry is wellpositioned to benefit from this surge, as companies seek to integrate Al into their products. Al has the potential to revolutionize patient care by enhancing efficiency and uncovering new possibilities for innovation. However, as with any emerging technology, regulatory considerations will play a crucial role. It will be essential to monitor potential regulatory developments to ensure they do not hinder the growth and adoption of Al-driven medical devices.



#### **Telemedicine & Remote Monitoring**

The expansion of telemedicine and remote patient monitoring has accelerated in recent years, driven by the growing demand for accessible healthcare. Similar to the rise of e-commerce platforms like Amazon, consumers increasingly seek convenient, at-home solutions for their healthcare needs. This shift presents a significant opportunity for medical device companies to develop and and enhance remote diagnostics patient care technologies. Companies within the industry are wellpositioned to capitalize on this trend by innovating solutions that meet the evolving demands of patients and healthcare providers.

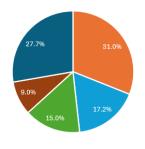
# **Personalized & Precision Medicine**

Advancements in technology have created opportunities for the development of personalized medical devices tailored to individual patient needs. These innovations range from customized implants to targeted drug delivery systems, enhancing treatment effectiveness and patient outcomes. This presents a significant opportunity for companies within the medical devices industry to establish a strong presence in this growing segment.

# **COMPETITIVE LANDSCAPE**

The Medical Devices industry is comprised of many large companies that lead the industry's competitive landscape. The industry is highly competitive as companies attempt to claim higher market share to benefit from the expected tailwinds relating to the aging population and the potential of Al integration.

Below is a figure showing the major players within the medical devices industry based on industry specific revenue forecasts for 2025:



Medtronic
Abbott Laboratories
General Electric
Danaher Corp
Other

Source: IBISWorld



The companies in focus for this report will be Abbott Laboratories (ABT), Medtronic (MDT), Stryker (SYK), and Boston Scientific (BSX).

# Abbott Laboratories (ABT)

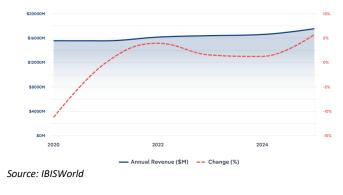
Abbott Laboratories is a prominent entity within the Medical Devices industry. In the third quarter of 2024, Abbott's Medical Devices segment reported a 13.3% organic sales growth, with notable contributions from areas such as Diabetes Care, Structural Heart, Heart Failure, and Electrophysiology. Key products driving this performance included FreeStyle Libre<sup>®</sup>, Navitor<sup>®</sup>, TriClip<sup>®</sup>, Amplatzer<sup>®</sup> Amulet<sup>®</sup>, and AVEIR<sup>®</sup>.<sup>14</sup>





# **Medtronic (MDT)**

Medtronic holds the largest share of the medical devices market, solidifying its position as a leader in technological innovation and advancement. The company specializes in the development, manufacturing, and distribution of a diverse range of medical technologies, including cardiovascular devices, surgical solutions, diabetes management products, and neuromodulation therapies. Medtronic's commitment to research and development (R&D) drives its portfolio expansion, integrating cutting-edge technologies like artificial intelligence (AI). With a robust global presence and widespread market reach, Medtronic is firmly established as a key player in the medical devices industry.<sup>15</sup>





# Stryker (SYK)

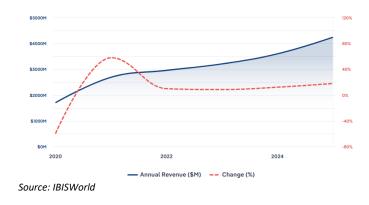
Stryker Corporation is a global leader in medical technology, focused on developing, manufacturing, and distributing medical devices. Its products include orthopedic implants, surgical tools, neurovascular devices, and emergency medical equipment. The company operates through three main segments: Orthopaedics (joint replacement and trauma implants), MedSurg (surgical and emergency medical supplies), and Neurotechnology and Spine (neurosurgery and spinal care). Stryker's strong R&D investment, including AI integration, reinforces its leadership in advancing patient care and outcomes.<sup>16</sup>





# **Boston Scientific (BSX)**

Boston Scientific develops and markets medical devices across a wide range of specialties, including MedSurg and Cardiovascular. The company offers products for diagnosing and treating gastrointestinal, pulmonary, urological, neurological, and cardiac conditions. Their portfolio includes devices for chronic pain management, spinal cord stimulation, coronary artery disease, and aortic valve conditions, along with specialized tools for cancer treatment, rate and rhythm heart disorders, and peripheral diseases. Headquartered in Marlborough, Massachusetts, Boston Scientific is a leader in providing innovative medical solutions worldwide.<sup>17</sup>







# **Peer Group Metrics**

#### Below shows profitability metrics for the peer group:

Company (Ticker)	Gross Margin	Operating Margin	Net Margin	
Abbott Laboratories (ABT)	50.83	16.33	31.83	
Intuitive Surgical (ISRG)	67.46	28.12	27.81	
Boston Scientific (BSX)	61.63	15.73	11.07	
Stryker Corporation (SYK)	61.82	22.35	13.25	

Source: FactSet—for 2024

#### Below shows capital structure metrics for the peer group:

Company (Ticker)	Total Debt to Equity	Total Debt to Total Asset
Abbott Laboratories (ABT)	28.37%	18.76%
Intuitive Surgical (ISRG)	0.89%	0.78%
Boston Scientific (BSX)	51.58%	28.50%
Stryker Corporation (SYK)	66.43%	32.86%

Source: FactSet—for 2024

# Below shows the geographical breakdown of sales for the peer group:

% International Sales	% Domestic Sales (U.S.)
61%	39%
33%	67%
39%	61%
25%	75%
	61% 33% 39%

Source: Company 10-Ks—for 2024

As shown in the tables above, Intuitive Surgical and Abbott Laboratories appear best positioned among their peers based on the financial and operational metrics provided. Intuitive Surgical stands out for their strong profitability and extremely low debt, suggesting both operational efficiency and financial flexibility. Abbott Laboratories also performs well, particularly with its high net margins and broad international exposure, positioning it to capitalize on global healthcare demand. In contrast, Boston Scientific and Stryker show more modest profitability and rely more heavily on debt financing, which could introduce greater financial risk, especially in uncertain macroeconomic environments. Stryker's heavy reliance on domestic sales may also limit its growth potential compared to more globally diversified peers. Collectively, these metrics suggest that Intuitive Surgical is the most conservatively managed and profitable, while Abbott offers a strong global footprint and solid margins, making them the more attractive companies within this peer group.

# **REGULATORY ENVIRONMENT**

As mentioned earlier, the regulatory environment is vital to the development and growth of companies in the medical devices industry. The primary regulatory body in the U.S. is the FDA, which oversees the safety and



effectiveness of medical devices. High-risk devices, such as implantable devices, life-support devices, and invasive devices, must undergo premarket approval (PMA). In contrast, moderate-risk devices, such as X-ray machines, blood pressure cuffs, and contact lenses, require 510(k) clearance. The FDA ensures that all medical devices meet rigorous safety and quality standards before they are approved for sale and use, and continues to monitor products on the market to ensure ongoing compliance and safety<sup>18</sup>

Companies with the largest market share in the medical devices industry typically operate on a global scale. As such, it is important to understand how medical device regulations differ by region and to highlight the key agencies responsible for overseeing safety and compliance.

# **European Medicines Agency (EMA)**

The European Medicines Agency (EMA) plays a central role in evaluating and monitoring medical devices within the European Union. It provides the Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) as frameworks for approving and overseeing medical devices in the EU market.<sup>19</sup>

#### **Health Canada**

The Health Canada agency is the regulatory power within Canada that regulates the safety and performance of medical devices. They follow international standards to provide a regulatory framework for medical devices pertaining to global trade.<sup>20</sup>

# **Therapeutic Goods Administration (TGA)**

The Therapeutic Goods Administration (TGA) is the regulatory agency in Australia. They provide guidelines for medical devices to ensure they meet the required standards before being marketed.<sup>21</sup>

#### Japanese Pharmaceuticals & Medical Devices Agency

The Japanese Pharmaceuticals & Medical Devices Agency (PMDA) provides regulation for medical devices in Japan. They offer a comprehensive system regarding device approval, monitoring, and post-market surveillance.<sup>22</sup>



# Brazilian Health Regulatory Agency (ANVISA)

The Brazilian Health Regulatory Agency (ANVISA) oversees regulations for medical devices within Brazil. They ensure safety before being marketed for use and that products are compliant with imposed international standards.<sup>23</sup>

# **Device Classifications**

The FDA classifies medical devices into three categories (Class I to Class III) based on their level of risk, which in turn determines the specific approval process required for each device.

Below is a graphic that describes the classification:

The classifications can be described as follows:

#### Low Risk (Class I)

- Devices that present minimal potential to harm users (e.g., elastic bandages and toothbrushes)
- 35% of device types are Class I and 93% are exempt from premarket review
- Most of these devices do not require clinical evidence for safety and efficacy

## Moderate Risk (Class II)

- Devices with moderate risk of harm (e.g., powered wheelchairs and needles)
- 53% of device types are class II, most of which require the 510(k) process
- Clinical evidence is often required, but at a level that is less stringent than for Class III devices

#### High Risk (Class III)

- Devices that sustain or support life are implanted, or that are high risk of injury or illness (e.g., pacemakers)
- 9% of device types are Class III and require the premarket approval (PMA) or humanitarian device exemptions (HDE) process
- Investigational device exemption (IDE) are typically required for a device to be used in a clinical study to collect safety and efficacy data

Source: CFRA Research



# FDA Approval Process<sup>24</sup>

For companies to legally be able to commercialize their products, they must submit their product through the appropriate approval processes:

# Premarket Notification 510(k)

A process used for low to moderate risk devices, and those with a similar predecessor device.

## **De Novo Process**

A process for low to moderate risk devices without a predecessor device to gain classification as Class I or Class II. Additionally, may use the 510(k) process.

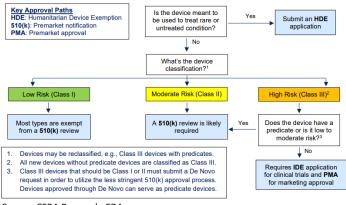
# Premarket Approval (PMA)

A process which involves FDA review to evaluate the safety and effectiveness of devices classified as high risk (Class III).

# **Humanitarian Device Exemptions (HDE)**

A process which allows for devices to be marketed without proven effectiveness. This is mainly employed for devices that target patients with a rare disease or condition for which there are no alternatives.

#### Below is a simplified process decision chart:



Source: CFRA Research, FDA

# **MARKET & COMPETITIVE FORCES**

# **Threat of New Entrants (Low)**

The medical devices market is characterized by high barriers to entry, which include significant research and development (R&D) expenditures, strict regulatory



requirements, and entrenched competition from established players. New entrants face substantial challenges in financing the R&D needed to develop products that offer improvements over existing devices. The approval process is also complex, with extensive clinical testing and FDA documentation required. Moreover, competition from experienced manufacturers, brand loyalty from physicians, and the difficulty of securing reimbursement from third-party payers make it difficult for new entrants to gain market share.<sup>25</sup>

# **Bargaining Power of Suppliers (Low to Moderate)**

The medical devices industry has numerous suppliers globally, which diminishes supplier power. However, some suppliers that provide specialized or unique components that are not easily substitutable may hold more bargaining power. Additionally, suppliers in this industry are often subject to stringent regulatory requirements, which further emphasizes the importance of consistency and reliability in meeting these standards.<sup>25</sup>

# **Bargaining Power of Customers (Moderate)**

Healthcare providers, particularly hospitals, are the primary buyers in the medical devices industry. The consolidation of healthcare providers has increased their leverage, enabling them to negotiate better pricing and reimbursement rates. Large provider organizations are also attractive to customers due to their ability to negotiate favorable insurance reimbursement rates. However, the bargaining power of buyers is lower for products with no substitutes or those deemed essential for specific healthcare needs.<sup>25</sup>

# Degree of Rivalry/Competition (High)

The medical devices industry is highly competitive, with numerous companies vying for market share. The rapid innovation and short life cycles of devices contribute to intense rivalry, as next-generation products often replace older versions quickly. Even market leaders can lose their technological dominance as competitors invest heavily in R&D and mergers and acquisitions (M&A) to penetrate new markets.<sup>25</sup>

# Threat of Substitutes (Low to Moderate)

The threat of substitutes in the medical devices industry is generally low for expensive and large equipment, such as robotic surgery platforms. The switching costs associated



with such equipment are high, including the cost of retraining staff and writing off old equipment. However, for smaller devices, the threat of substitution is moderate, as physicians may be reluctant to switch due to the potential for adverse patient outcomes and the time needed to familiarize themselves with new products. Product differentiation also takes time, as new devices often require follow-up studies to demonstrate their value.<sup>25</sup>

# **ECONOMIC OUTLOOK**

#### **Global Trade Policy Uncertainty**

One of the main considerations for the medical devices industry is the new administration and its proposed plans for the healthcare sector. We have already seen proposed tariffs on Canada, Mexico, and China implemented, although these tariffs have been paused as of February 2025. The global economic environment is becoming increasingly complex as we look to the future, particularly due to uncertainty around policies like tariffs, which place pressure on manufacturers, including those in the medical devices industry.

# AI & Technical Advancements

While the new administration's policies will significantly impact manufacturers in the medical devices sector, we believe they will benefit from the current AI tailwind. We are witnessing an exciting climate surrounding global AI companies and the innovations they offer. Large companies like NVIDIA, which dominate the AI industry, show no signs of slowing down in terms of technological advancements. We anticipate that the medical devices industry will follow suit, benefiting from this new era of technological progress, largely driven by AI.

#### **Unemployment Rate**

As mentioned <u>previously</u>, the unemployment rate is a key economic indicator that can significantly impact the medical devices industry. Higher unemployment often results in fewer individuals receiving employer-sponsored health insurance, which reduces access to non-essential medical care. As a result, demand may decline for elective procedures and the associated medical devices, such as orthopedic implants or surgical tools that are not critical for immediate survival. While life-saving devices may still see stable demand, companies with greater exposure to



elective procedures could experience revenue pressure during periods of elevated unemployment.

# **Exchange Rates**

Exchange rates are an important economic factor for the medical devices industry, particularly for companies with a significant international presence. Fluctuations in currency values can materially impact a company's bottom line as they translate foreign revenues and expenses back into their home currency. A stronger domestic currency can reduce the value of international sales, while a weaker currency can increase reported costs abroad. These foreign exchange movements can lead to losses that must be accounted for in earnings, potentially masking underlying business performance. For companies with a large share of international revenue such as Abbott Laboratories, monitoring exchange rates is essential because they can have a direct and meaningful effect on financial results and future outlook.

Overall, the medical devices industry is influenced by several key economic factors, including trade policy uncertainty, technological advancements, unemployment, and exchange rates. While tariffs and global policy shifts may pressure manufacturers, innovation driven by AI presents strong growth potential. At the same time, unemployment and currency fluctuations can materially impact demand and earnings, especially for companies with international operations.

# CONCLUSION

The medical devices industry is well-positioned for sustained growth, supported by technological advancements, an aging global population, and increasing demand for innovative healthcare solutions. The recovery in elective procedures post-pandemic, along with rising investment in Al-powered diagnostics, robotic-assisted surgery, and remote patient monitoring, continues to drive industry expansion. Strong R&D spending further reinforces the sector's long-term potential.

However, the industry faces challenges, including regulatory hurdles, shifting trade policies, and reimbursement pressures that could impact profitability. Additionally, the rising influence of GLP-1 weight loss drugs may reduce demand for certain devices, particularly those used in bariatric procedures.



As a fund, we believe the most attractive investment opportunities lie in companies with diversified product portfolios, strong global presence, low financial leverage, and a proven ability to innovate. Abbott Laboratories and Intuitive Surgical exemplify these characteristics. Abbott's broad international footprint and balanced portfolio position it well for global growth, while Intuitive Surgical's strong margins and leadership in robotic-assisted surgery highlight its innovation-driven model. Conversely, we remain cautious toward companies heavily reliant on elective procedures or with limited international exposure and higher debt burdens, as they may be more vulnerable to macroeconomic and regulatory headwinds.



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