

Over the past 20 years, the medical device industry has experienced exponential growth. In the past few years alone, the industry has added a third of its production capacity, and the industry is expected to continue to grow at a rapid pace. This growth has led to a significant increase in the number of medical devices on the market.

Growth of the Medical Device Industry



US Medical Device Revenues

The US medical device industry is expected to reach \$100 billion in 2016, up from \$50 billion in 2009. This growth is driven by a number of factors, including the aging population, the increasing prevalence of chronic diseases, and the growing demand for minimally invasive surgical techniques. The industry is also seeing a shift towards higher-value devices, such as those used in minimally invasive surgery and cardiac care.

Levels of FDA Classification

Class I Devices
These devices are considered to be of low risk. They are subject to the least stringent regulatory controls. Examples include band-aids, tongue depressors, and manual stethoscopes.

Class II Devices
These devices are higher risk than Class I devices. They are subject to more stringent regulatory controls, including the requirement for premarket notification (510(k)). Examples include cardiac catheters, infusion pumps, and manual resuscitators.

Class III Devices
These devices are considered to be of high risk. They are subject to the most stringent regulatory controls, including the requirement for premarket approval (PMA). Examples include heart valves, implantable cardiac devices, and power morbidly obese (PMO) devices.

Expansion of High Risk Devices

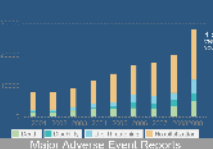


Premarket Approvals (PMA)

The number of premarket approvals (PMA) has increased significantly over the past few years. This is due to the expansion of high-risk devices into the market, as well as the increasing number of Class III devices. The FDA has also been more proactive in reviewing PMA applications, leading to a higher number of approvals.

Rise in Adverse Events

Over the past few years, there has been a significant increase in the number of adverse events reported to the FDA. This is due to a number of factors, including the increasing number of medical devices on the market, the growing awareness of medical device safety, and the increasing number of reports from healthcare providers and patients.

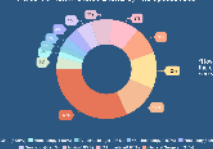


Major Adverse Event Reports

The number of major adverse event reports has increased significantly over the past few years. This is due to a number of factors, including the increasing number of medical devices on the market, the growing awareness of medical device safety, and the increasing number of reports from healthcare providers and patients.

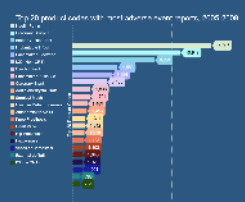
Hot Spots for Patient Risk

There are several areas of the medical device industry that are considered to be high risk for patient injury. These include cardiac devices, implantable medical devices, and minimally invasive surgical techniques. The FDA has been particularly active in reviewing devices in these areas, and has issued several recalls in the past few years.



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Diving Deeper



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