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ORIGINAL ARTICLE **OPEN ACCESS**

Traversing the Regulatory Environment: Approvals and Retrievals of Medical Devices through USFDA (2019 – 2023)

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ABSTRACT
Medical Devices play a vital role in various aspects of healthcare, and advances in science & technology of medical industry is coming up with innovations. The role of AI in medical devices where the large tech companies have been accelerating in developing smart products, such as smart wearables. Many of them are using AI and developing new AI applications to bring new, innovative, patient friendly functionalities. This study examines the approvals and recalls of medical devices with their assigned classes during the span of 2019-2023. About 99% of approvals of Class-3 devices whereas the recalls of Class-1(7.04%), Class-2 (78.8%) and Class-3 (14.09%) and these carry great dangers, show different patterns of clearance. All Classes show an increasing trend in recalls, and common causes include defects in production, poor quality control, malfunctioning software, and incorrect labelling. Ultimately this research highlights the crucial importance of continuous post-market surveillance, flexible regulations, and thorough studies to improve safety practices and foster creative breakthroughs in medical device technology.
Keywords: *Medical Devices, Food and Drug Administration, Approvals, Recalls, Center of Disease Radiological Health (CDRH).*

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INTRODUCTION

Medical Device Industry which is a predominant one in the Health Care Sector nowadays involves in treating of the Diseases simultaneously for the Diagnostic purposes. Medical devices encompass a wide range of products, from simple tools like thermometers and blood pressure monitors to complex devices such as MRI machines and pacemakers. These devices contribute to the diagnosis and treatment of diseases, monitoring of vital signs, and improvement of overall healthcare outcomes. In most countries, medical devices are classified as health items for regulatory purposes and are distinguished from pharmaceutical based on how they function. Unlike medications, medical gadgets operate mechanically or physically and do not depend on metabolism to accomplish their primary purpose (1). They play a prominent role in various health care settings including hospitals, clinics, and home health care. This Industry operates globally with companies engaging in international markets. There is a fascinating growth in the medical device industry in terms of the revenue and also in the technological sophistication, due to the advent of the AI in medical devices which could serve in many things like monitoring, medical imaging, robotic surgeries, virtual nursing assistants, precision medicine and digitalization which serves as a catalyst for innovation, fostering advancements in connectivity and enhancing capabilities related to data management. The medical device industry is facing regulatory challenges with stringent requirements, evolving regulation, global harmonization, cyber security concerns, and post market surveillance. The development and the deployment of medical devices are subjected to rigorous regulatory frameworks to ensure their safety, efficacy, and quality. Regulatory agencies such as the U.S. Food and Drug Administration and the European Medicines Agency (EMA), oversee the approval and market entry of medical devices, contributing to the overall safety and effectiveness of these critical health care tools. AI has the potential to significantly impact the medical device industry by introducing innovative solutions that enhance efficacy, accuracy, and personalized patient care. The FDA has defined the medical device a product to be a device, and subject to FDA regulation, if it meets the definition of a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act.

Per Section 201(h)(1) of the Food, Drug, and Cosmetic Act, a device is: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
(A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o). (2) The FDA has classified the Medical Device classification system based on their risks and their regulatory controls in order to provide an assertiveness in terms of the safety and effectiveness of the medical device. (3) Figure (1).

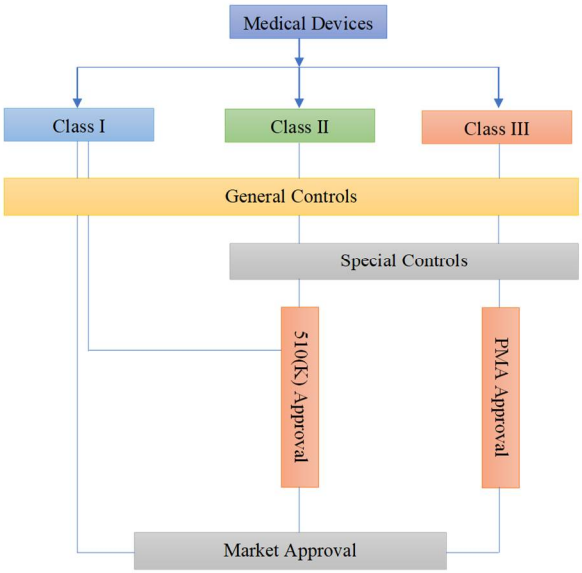

Figure 1: Classification of Medical Devices (USFDA).

The code of federal regulations in the United States is a comprehensive compilation of enduring regulations promulgated by the federal executive departments and agencies which were organizes into 50 titles, each delineates expansive subject areas subject to continuous federal oversight and regulatory measures (4), whereas the e-CFR which is an online one where we can see this 50 titles under this the tile 21 which delas about the Food and Drugs (5) under the chapter I there are 12 subchapters which are denoted as alphabetically wise (6) subchapter H which deals about the medical devices (7) whereas the 21 CFR Part 810 encompasses about the Medical Device Recall Authority (8) simultaneously the 21 CFR Part 814 which is a Pre-Market Approval of Medical Devices (9). The public's health is the primary concern of the Center for Devices and Radiological Health (CDRH). We make certain that patients and doctors have prompt access to safe radiation-emitting products and top-notch medical equipment. We make publicly available, easily understandable science-based information regarding the commodities under our supervision available to consumers, patients, and their caregivers. By developing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory processes, and guaranteeing consumer confidence in devices commercialized in the US, we encourage medical device innovation. Americans are the first people in the world to have access to high-quality, safe, and efficient medical devices that are essential to public health. The United States leads the world in regulatory science, medical device creation and manufacturing, and radiation-emitting product safety. The post-market monitoring system in the United States effectively identifies devices that are operating poorly, provides an accurate description of their practical effectiveness, and expedites the certification or clearance of such goods. Devices that are nonetheless high-quality, safe, and functional are sold legally in the United States. Consumers, patients, caregivers, and providers can use easily understandable scientific information regarding medical equipment to help them make decisions about their health (10). Medical Device Recall is a unilateral gauge

adopted by the manufacturers to remove or rectify products that violate regulations set forth by the Food and Drug Administration, such as fraudulent labelling. If the manufacturer neglect to recall the unsafe device the FDA has the supremacy to mandate a recall from the manufacturer (11) simultaneously the pathways to market a device there ae some renowned pathways to get an approval for marketing the device those are primarily 510(k) pathway requires proof that the device is substantially equivalent to a legally marketed device and the Pre-Market Approval refers to the scientific and regulatory review to evaluate safety and effectiveness of the class III and it is the most involved process Devices types that have never been marketed in the U.S., yet possess a well-established understanding of their safety profile and technology all these aspects ae discussed in the "De Novo" these are the pathways which were paved the ways for the marketing of a Medical Device. In an attempt to expedite the process, the Food and Drug Administration Modernization Act of 1997 introduced the "least burdensome" premarket review standards and allowed third parties to conduct premarket reviews. Clinical data from previous versions of the device may be submitted for premarket filings by new generations of the device. The De Novo program was created as a result, enabling the classification of new, low-to-moderate risk devices as Class I or II risks (12). The FDA evaluation procedure is determined on the device's classification. Class I equipment is subjected to the least extensive evaluation, which is usually administrative in nature. The review team assigns 510(k) submissions to tiers according to the risk level of the device. Tier 1 categories are the most basic. With an emphasis on the labeling requirement, administrative review is utilized to confirm the considerable equivalence of certain tier 1 devices. Devices in Tier 2 are slightly more sophisticated. Tier 2 devices undergo a scientific review in addition to the administrative evaluation, which is typically completed by a single lead reviewer. Tier 3 devices are the most complicated 510(k) applications; a group of specialists conducts a thorough scientific investigation, which frequently involves a review of clinical data. A scientific panel provides feedback on PMA applications involving Class III devices. Every time a new model or product is released, there is more communication between the company and the scientific panel. "The new model medical device development process" (MDDP) is the term used to describe this method for experimental devices that are part of PMAs. These parties convene to deliberate and determine what is needed to have a product approved. Consequently, MDDP makes it possible for the FDA scientific panel and the manufacturer to work together early on in the device's research and product preparation stages (13).

MATERIAL AND METHODS

The Dataset is originated from the Authoritative U.S. Food and Drug Administration website, we have discerned the approvals and recalls of the medical device period spanning from 2019-2023. Our approach involves meticulous categorization of medical device class based on their class. In case of approvals, a comprehensive dataset has been complied with, capturing year-wise data over the last half-decade. Each approved device is associated with a unique entry in the PMA database, allowing us to extract the product code associated with each device. This product code serves as basis for categorizing the devices based on their class. Simultaneously, for recalls, pertinent information is obtained from dedicated pages on the FDA website (14). This meticulous process ensures a thorough exploration of medical devices in the context of their regulatory status, providing a nuanced understanding of trends and patterns over the specified time frame. This categorization approach, encompassing both approvals and recalls, lays the groundwork for a comprehensive analysis that aims to contribute valuable insights to the field of medical device regulation. FDA uses the term "recall" when a manufacturer takes a correction or removal action to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health. A medical device recall does not always mean that you must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed. If an implanted device (for example, an artificial hip) is recalled, it does not always have to be explanted from patients. When an implanted device has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place (15, 16). Device recalls impose substantial burdens, in terms of health and economics (17). Medical device regulation in the United States is the responsibility of the Food and Drug Administration (FDA), specifically the Center for Devices and Radiological Health (CDRH). The FDA divides devices into three classes: Class I, II, and III. Regulations and controls apply differently to each sort to varying degrees. While Class I devices, which are considered low-risk, adhere to fundamental controls, Class II devices require additional particular controls, such as performance standards and post-marketing monitoring. Because they are essential to preserving human life, Class III devices are subject to the strictest regulations. Before these devices may be approved through a PMA application, they usually need to undergo clinical research. Before approving Class II 510(k) clearances and Class III PMAs, the FDA carefully reviews the safety and efficacy evidence. To protect the public's health, the regulatory system makes sure that medical devices in the US adhere to strict criteria

(18). Figure (2). The FDA classifies recalls as I, II, or III depending on the proportionate amount of health risk the recalled product poses. Class I refers to situations in which there is a reasonable chance that using or coming into contact with a product that is illegal would have a detrimental impact on one's health or possibly result in death. Class II describes situations in which there is little likelihood of significant negative health impacts, or in which using or being exposed to a violative product may result in short-term, medically treatable health consequences. Class III: a situation where there is minimal possibility of negative health consequences from consuming or encountering a product that violates the law (19). The FDA Recall database holds information on medical equipment that has been recalled for a multitude of reasons. This database is a vital resource for healthcare professionals, patients, and the general public to be informed about potential medical device safety risks. The database is frequently updated to reflect new recalls, revision, or other pertinent information. This ensures that users have access to the most recent information about medical device recalls. The Recall database has the following:

1. Product Name
2. Product code
3. In Vitro Devices
4. Recall class
5. PMA/510(K) Number
6. Recall Date
7. Reason for Recall
8. Recalling Firm
9. Root Cause

This holistic strategy underscores the FDAs commitment to sustain the highest levels of safety and efficacy in the field of medical devices.

RESULTS

Table (1) presents a detailed overview of approved medical devices categorized by risk classes (Class 1, Class 2, and Class 3) from 2019 to 2023. The numerical values in the table represent the count of approvals for each class and year. In 2019, Class 1 and Class 2 had no approvals, while Class 3 had 43 approvals. This trend continued, with no approvals for Class 1 or Class 2 in subsequent years. The count of approved Class 3 devices fluctuated, reaching a peak of 56 in 2020. Figure (3) visually illustrates the dynamic changes in approvals across all classes from 2019 to 2023. The data from 2019 to 2023 provides insights into the regulatory framework and market entry dynamics for medical devices across risk categories. Class 1 devices showed a consistent absence of approvals, potentially indicating a limited market presence or an expedited regulatory pathway. Class 2 devices had minimal approvals in 2019 and 2020, with none reported in 2021, 2022, and 2023. Variations in Class 2 approvals may be attributed to technological advancements or changes in consumer preferences. Class 3 devices, with higher risk profiles, displayed a fluctuating pattern of approvals, notably increasing over the years. This suggests evolving industry trends, changes in governmental scrutiny, or shifts in risk-benefit analysis. A comprehensive evaluation of approved Class 3 devices, considering intended use, technological advancements, and therapeutic indications, could offer valuable insights into the regulatory landscape's intricate dynamics. This analysis contributes to a deeper understanding of factors influencing the approval processes for higher-risk medical devices. This study conducts a thorough examination of the annual counts of recalled medical devices, leveraging data reported by the US Food and Drug Administration (USFDA) for three distinct classes (Class-1, Class-2, and Class-3) from 2019 to 2023. Table (2) outlines the specific counts of recalled devices within each class, revealing notable trends over the designated period. Figure (4) visually represents these trends, highlighting an observable increase in recalls across all classes. To provide a comprehensive overview, Table (3) compares the total, approved, and recalled counts of medical devices for each year from 2019 to 2023. This comparison underscores the dynamic relationship between device approvals and recalls, with fluctuations evident in each year. Figure (5) complements this analysis by illustrating the percentage distribution of approved and recalled medical devices, offering a nuanced perspective on the regulatory landscape. The identified trends prompt a detailed investigation into the factors contributing to the escalating recalls, particularly for Class-1 and Class-2 devices. Class-1 devices, traditionally considered low risk, exhibit a noteworthy rise in recalls, necessitating in-depth analysis to uncover root causes. The varied pattern in Class-2 recalls underscores the importance of ongoing monitoring and regulatory oversight. Moreover, the fluctuating nature of Class-3 recalls suggests influences from changing risk assessments, regulatory adjustments, or advancements in post-market surveillance techniques. This study contributes valuable insights to the discourse on medical device safety by examining the annual counts of recalled devices and comparing them with approved devices. The findings have implications for regulatory

frameworks, device safety assessments, and strategies for post-market surveillance, enhancing our understanding of the intricate dynamics surrounding medical device recalls.

DISCUSSION

The given dataset encompasses every year's shift in medical device approvals and recalls across three unique classes denoted as Class-1, Class-2, and Class-3 as reported by the US Food and Drug Administration (USFDA) from 2019 –2023. This in-depth research reveals nuanced patterns in the regulatory environment, providing useful insights into the lifetime of medical devices, which includes their entry to the market and subsequent post market surveillance. The trends that have been noted in both approvals and recalls illustrate the convoluted interplay between regulatory supervision, advancements in technology, and risk evaluation in the medical device market. Prospective research should focus on the precise characteristics and circumstances surrounding both approved and recalled devices in order to improve our understanding of the regulatory systems that govern medical devices and improve patient safety. Regarding Class-1 devices there are consistently no official approvals within the necessary time frame. This consistent absence of regulatory approvals is consistent with the established low risk classification of Class-1 devices, indicating adherence to shortened regulatory routes and emphasizing the supposed safety and low inherent risk associated with this category of medical equipment. Regarding Class –2 devices, the information gathered illustrates a trend of irregular approvals, with one recorded permission for each year between 2019-2023. This inconsistent clearance profile shows that devices in the moderate-risk category will require continuing regulatory involvement. The repeated nature of these approvals necessitates more examination to identify the specific variables guiding legislative decisions such as changing technical paradigms, adjustment to risk assessments techniques, or responses to changing market demands. On the other hand, Class-3 devices which have been recognized by higher risk in the profile show variations in the number of approvals through this portion of the study. Notably, approvals grow from 43 in 2019 to 56 in 2020, with additional variations in the later years. This dynamic pattern may indicate shifting attention from regulators, changes in risk-benefit calculations, or reactivity to technological improvements in the higher-risk medical device market. Recalls for Class-1 devices increased noticeably between 2019 and 2023, totaling eight recalls, according to the statistics. Class-2 devices show swinging objects with 36 recalls in 2019, 25 in 2020, 45 in 2023. Class-3 devices demonstrate unpredictability, with a peak of 13 recalls in 2021 and stabilizing at four recalls in 2022 and 2023. These patterns illustrate the dynamic nature of post-market surveillance and regulatory management, necessitating a more in-depth investigation of the precise causes of recalls in each device class. The terrain of medical device recalls is complex, demanding a thorough investigation to comprehend the complexities that lead to such incidents. We investigated the causes of these recalls, concentrating on three key dimensions: manufacturing issues, quality challenges, software malfunctions and a few labelling errors. Manufacturing errors are the frequent cause of medical equipment recalls. Although technological breakthroughs and strong quality control methods, the complexities of making delicate medical equipment can sometimes results in unanticipated failures. These faults in material, design miscalculations, or issues that arise during the manufacturing process are examples of these errors. The impact of manufacturing errors on patient safety and device efficacy highlights the significance of continuous process improvement and strong quality procedures. Quality issues, as opposed to manufacturing faults, cover a larger range of concerns about the overall structure and durability of medical devices. Thes issues could be the result of poor material choices, inefficient assembly techniques, or flaws in gadget components. Addressing quality issues is crucial for ensuring medical device durability and reliability, which leads to better patient outcomes and reduces the likelihood of recalls of medical devices. The predominance of software problems in recalls is a notable trend at an era when health care devices rely on complicated software. The complex interaction of hardware and software components produces complexity that, if not appropriately managed, can lead to failures. In correct data interpretation, device misalignment, or, in severe circumstances, system failure can all result from software errors. Errors in labelling turn out to be another important reason in health-related product recalls. For medical practitioners to be sure that their equipment is utilized correctly, labels must be clear and precise. Patient safety may be jeopardized by factual or interpretive labelling errors because they may be misapplied or misinterpreted. Manufacturers, authorities, and consumers need to communicate clearly and pay close attention to details in order to resolve labelling difficulties.

Figure 2: Approval Process/pathways for Medical Devices.

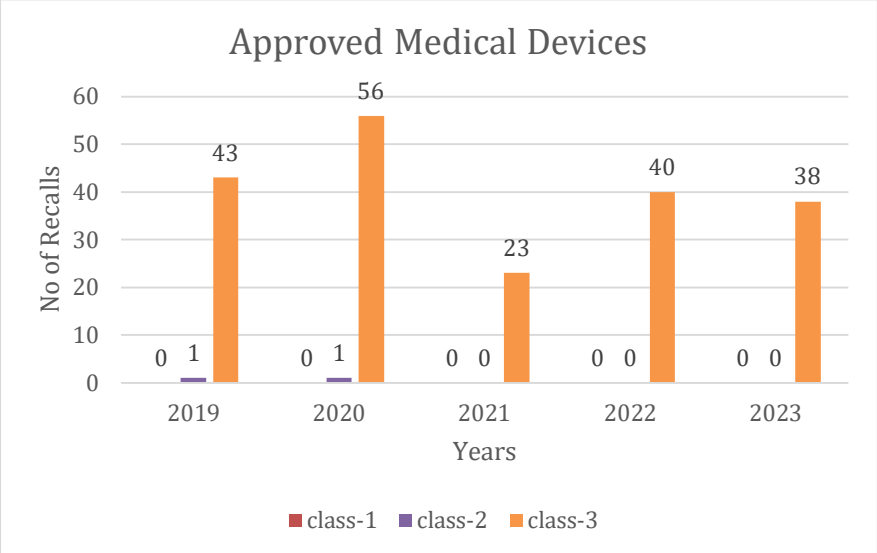

Figure 3: Number of Approved medical devices from 2019 - 2023.

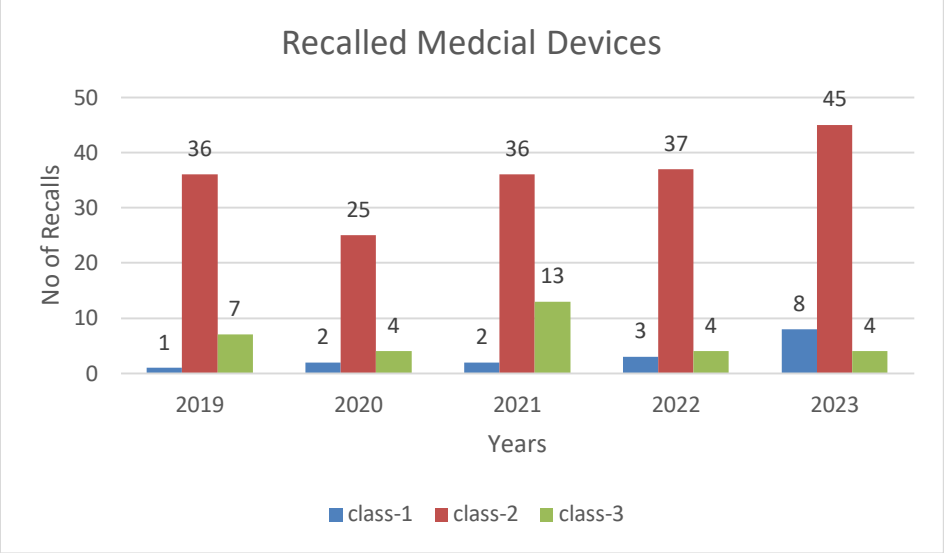

Figure 4: Number of Recalled Medical Devices.

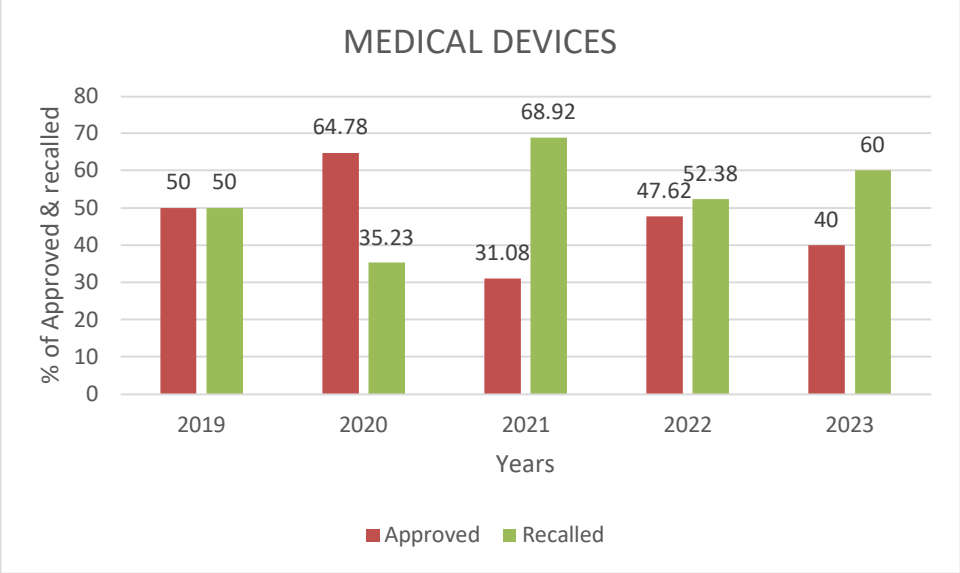

Figure 5: Comparison of percentage Approved & Recalled Medical devices (2019 -2023)

Table 1: Approved Medical Devices.

	2019	2020	2021	2022	2023
Class-1	0	0	0	0	0
Class-2	1	1	0	0	0
Class-3	43	56	23	40	38

Table 2: Recalled Medical Devices.

	2019	2020	2021	2022	2023
class-1	1	2	2	3	8
class-2	36	25	36	37	45
class-3	7	4	13	4	4

Table 3: List of Approved & Recalled Medical Devices (2019 – 2023)

Year	Total	Approved	Recalled
2019	88	44	44
2020	88	57	31
2021	74	23	51
2022	84	40	44
2023	95	38	57

CONCLUSION

To sum up, a thorough examination of medical device approvals and recalls across all regulatory classes spanning 2019 and 2023 reveals evolving trends in regulatory environment. The observed rise in Class-1 device approvals and the difference in Class-2 and Class-3 approvals demonstrate the constantly changing character of risk assessments and regulatory considerations. The ongoing lack of Class-1 device recalls is indicative of strong safety measures for low-risk equipment. However, the disparities in recall rates between Class-2 and Class-3 devices underscore the ongoing challenges associated with ensuring the efficacy and security of devices with elevated risk profiles. These findings highlight the importance of continuous post-market surveillance and adaptable strategies to address emerging safety concerns. These results underscore the significance of ongoing post-market surveillance, regulatory oversight, and flexible strategies to address emerging safety risks effectively. Further investigation and thorough examination of the unique attributes and circumstances surrounding approvals and recalls are imperative for enhancing device safety protocols, optimizing legislative frameworks, and stimulating inventive medical device innovation.

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REFERENCES

1. Limaye R, Fortwengel G. (2018). Review of new medical devices approvals by USFDA during the period of 2010 to 2014. International Journal of Clinical Trials. 5 (3):116-20.
2. https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device#introduction
3. https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification.
4. https://en.wikipedia.org/wiki/Code_of_Federal_Regulations
5. https://www.ecfr.gov/
6. https://www.ecfr.gov/current/title-21
7. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H
8. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-810?toc=1
9. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-814
10. https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-mission-vision-and-shared-values
11. Alfred Sarkissian, Falls Church, VA. (2019). USA An exploratory analysis of U.S. FDA Class I medical device recalls: 2014–2018. Journal of Medical Engineering & Technology. 42 (8): 1-9
12. Schlauderaff A, Boyer KC. (2019). An overview of food and drug administration medical device legislation and interplay with current medical practices. Cureus. 9;11(5).
13. Sucher JF, Jones SL, Montoya ID. (2009). An overview of FDA regulatory requirements for new medical devices. Expert Opinion on Medical Diagnostics. 1;3(1):5-11.
14. https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls
15. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
16. Sethi R, Popli H, Sethi S. (2017). Medical devices regulation in United States of America, European Union and India: A comparative study. Pharm. Regul. Aff. 20;90-98
17. Sravya P. Vajapey, MD, MBA, Mengnai Li, (2020). Medical Device Recalls in Orthopedics: Recent Trends and Areas for Improvement. The Journal of Arthroplasty. 2020 (1-8)
18. Teresita C. (2020). Using the FDA MAUDE and Medical device Recall Databases to Design Better Devices Bio medical Instrumentation & Technology.2020: 178
19. https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices

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