Approved, Implanted, Recalled: What Cardiovascular Device Failures Reveal About Regulatory Oversight

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Abstract—**High-risk cardiovascular medical devices are essential for patient survival, yet they account for a number of serious device recalls among FDA-approved categories. Despite pre-market regulatory review and metrics, failures continue to emerge post-approval, raising questions about how effectively current regulatory frameworks predict device safety, engineering reliability, and long-term clinical performance. Furthermore, limited work has systematically compared regulatory performance metrics against established engineering standards and longitudinal patient outcomes. Because of this, it becomes important to evaluate FDA regulatory frameworks and actual performance for recalled cardiovascular devices to critique approval standards. Using a case study approach, our research examines whether existing regulatory metrics sufficiently capture risks that later manifest as device recalls. For this, the Medtronic Harmony Transcatheter Pulmonary Valve (TPV) System was chosen, as it is an FDA-approved device with a significant recall in its history and 47 device iterations, along with multiple sources of documented clinical trials. As an implantable device, it also enables long-term performance analysis across different device iterations. The primary purpose of this device is to treat severe pulmonary regurgitation in patients with native or surgically repaired right ventricular outflow tracts through transcatheter pulmonary valve replacement. The device was investigated through publicly available FDA post-market surveillance data, established standards (ISO), company reaction to device recall, clinical performance, long term patient outcomes, and device lifecycle documentation. Preliminary results suggest that current standards prioritize speed and innovation over safety and effectiveness. By the completion of this work, the study aims to propose evidence-based improvements to the regulatory approval of high-risk cardiovascular devices, enhancing pre-market review and post-market surveillance to better protect patient safety. In this paper, recommendations will be provided to improve regulatory review processes for cardiovascular medical devices. Future work will also be discussed.**

Keywords—medical device failures, FDA approved devices, Medtronic Harmony Transcatheter Pulmonary Valve, medical device regulatory oversight.

I. INTRODUCTION

Cardiovascular disease is the leading cause of death globally, accounting for an estimated 19.8 million deaths in 2022, illustrating the necessity of cardiovascular devices to mitigate the many cardiac risks [1]. The most prominent cardiovascular devices include pacemakers, stents, ventricular assist devices, and prosthetic heart valves. These devices are used to treat a variety of conditions such as heart arrhythmias, blocked arteries, poorly functioning heart valves, and heart failure. Such cardiovascular devices are invasive and present short-term and long-term risks; they also significantly improve the well being and likelihood of survival in patients [2]. While design and performance failures can have life-threatening effects for patients, regulatory processes help to minimize these risks. While the World Health Organization provides regulatory guidelines to establish international harmonization and ensure consistent safety standards globally [3], the Food and Drug Administration (FDA) in the United States has regulatory oversight over marketed medical devices and specific approval pathways based on risk level. Such regulations are essential for ensuring patient health and safety. The FDA classifies devices based on the risk they pose to the patient. The three classifications - Class I, Class II, and Class III - define the level of risk. Class I devices pose minimal risk and are subject to the least regulatory control. Examples include stethoscopes, bandages, or surgical gloves. Class II devices pose moderate risks and require additional regulatory oversight, subject to special controls for clearance. Examples of Class II devices include X-ray machines, contact lenses, and infusion pumps. Class III devices pose the greatest risk to patients and are subject to extensive regulatory controls for clearance. They are often used to support functions of life, and include devices such as prosthetic heart valves, implants, and pacemakers [4].

To ensure the effectiveness and safety of medical devices released to the market, the FDA primarily uses one of two approval pathways for domestic devices (**Figure 1**): (1) the Premarket Approval (PMA) pathway, and (2) the 510(k) pathway [5]. PMA is an evaluation process that requires thorough scientific review to ensure that high-risk, life-sustaining medical devices are safe and effective [5]. This approval pathway is required for Class III medical devices. Because devices must have their PMA application approved before release, the approval process relies on a medical device having sufficient scientific evidence. Manufacturers are required to provide documentation, with a non-clinical laboratory studies section and clinical investigations section, as part of their PMA application [5]. The 510(k) process is used for medical devices that do not require PMA approval [6]. This pathway applies primarily to Class I and Class II devices

entering the market. Manufacturers submit a 510(k) application demonstrating that the device is substantially equivalent to an existing legally marketed device. Substantial equivalence means the device has the same intended use and similar technological characteristics, or differences that do not raise new safety or effectiveness concerns, with supporting evidence showing comparable safety and performance [6]. Unlike the PMA pathway, the 510(k) process does not typically require clinical trials, instead relying on similarity to previously approved devices.

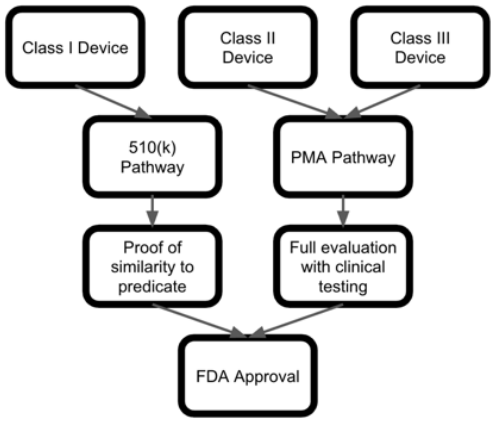

Fig. 1. Flow Chart of FDA Approval Pathway Processes.

After a device has been approved, the FDA has multiple strategies for monitoring and improving the device while it is on the market. One of the primary mechanisms for this is the use of PMA supplements, which are submissions made by manufacturers to report and gain approval for changes to an approved device; these supplements are categorized based on the type of modification, such as process changes (manufacturer / sterilizer/ packager / supplier), design changes, labeling updates, or post-approval study modifications [7]. Furthermore, these supplements are assigned sequential identifiers (e.g., S001, S002, S003), but they are not always released or approved in numerical order. [7]. Another mechanism for monitoring and improving devices comes from recalls. FDA-approved medical devices can be recalled for a variety of reasons, including labelling issues, employee error, use error, and integral software design issues, among over 25 other reasons. The FDA classifies these three recall categories as Class I, Class II, and Class III, based on level of risk and ranging from most to least severe respectively. Medical devices recalls are initiated either voluntarily by the manufacturer or mandated by the FDA when an issue arises, requiring either correction or removal from the market [8]. Class I recalls occur in the most serious situations, where there is a high probability that the use of the product could cause severe health consequences or death. Class II recalls occur when use of the product could cause temporary or reversible health consequences, or there is slight risk of serious harm to the patient. Class III recalls are the least severe and occur when use of the product is not likely to cause negative health effects, but the device violates regulatory standards, including issues with labeling or manufacturing [9].

Past studies have investigated recall rates and reasons for FDA approved devices. Our paper contributes to this body of knowledge. For instance, a study looking at recalled devices between 2014 and 2018 approved under either 510(k) or PMA pathways found that device design was the primary cause of recall for class III FDA devices, with another study noting that cardiovascular devices between the years 2014 and 2022 had the same most common recall reason of device design [10]. Several studies have shown higher recall risks for devices cleared through the FDA's 510(k) pathway. One investigation of orthopedic devices found that 510(k)-cleared devices were 11.5 times more likely to be recalled compared to those approved through PMA [11, 12]. Broader evidence shows that 510(k) devices not only have higher recall rates, but that these recalls are also increasing more quickly than those for PMA-approved devices [11, 12]. Additional research emphasizes the need for stronger safeguards in the 510(k) process, particularly to address issues with predicate device selection for patient safety [13]. These concerns are especially important for cardiovascular devices, which have the highest recall rates among medical devices, with roughly two-thirds approved through the 510(k) pathway [14]. Together, this underscores the need for more rigorous evaluation standards within the 510(k) approval process, particularly given its limited requirement for clinical trial data.

While general data on reasons for recall is valuable, it is equally important to examine research on specific past cardiovascular devices to understand prior approaches to device-specific analyses and to assess what is known about their long-term performance. There have been many reports that use clinical data to show the longitudinal performance of recalled devices still being used on patients. For instance, one report that focused on studying the long-term performance of the transcatheter aortic valve replacement and the surgical aortic valve replacement - both cardiovascular devices that were not recalled - used information from first implant records and 5 year echocardiograms to determine that both device's performance remained stable for living patients 5 years after implant [15]. From this, the 5-year echo data was collected through another report funded by Edward Life Sciences, the marketing company, where data was collected at 25 hospitals [16]. A similar approach was taken through another article that looked into five different cardioverter defibrillator leads using data from patients in the University of Pittsburgh Medical Center, where it was found that the two devices out of the five that were recalled performed substantially worse, shown through survival rates declining for them after 2 years [17]. However, it is important to note that all these devices were approved under the PMA pathway, and there is limited evidence of long-term follow-up data with devices approved under the 510(k) pathway. This is because devices that would still be in use, such as implantable devices, are class III and thus would be required to use the PMA pathway. Additionally, it is important to note that all of these studies used data from hospitals to draw conclusions about the long-term performance of a cardiovascular device, since hospitals have access to data on the devices that the manufacturers may not publicly show.

However, studies such as these tend not to analyze the device further than its longitudinal performance and often do not look at the complete history of the device. Based on this, to effectively analyze potential blind spots within regulatory approval and upkeep processes, it is first important to examine historical recall trends to identify common characteristics, recurring causes of failure, and potential oversights that may indicate weaknesses in current regulatory or design processes.

To analyze potential gaps in regulatory processes, a single-device case study approach was used in this paper. Rather than analyzing multiple devices at a surface level, focusing on a single device allows for an in-depth analysis of the approval pathway, recall history, and device supplements. This method allows for a clearer understanding of how steps in regulatory processes and patient outcomes are connected, along with how issues are identified and addressed from both the perspectives of the company and the FDA. From available FDA approved devices, the most commonly recalled devices were cardiovascular devices with design-related failures, particularly among Class III devices and Class I recalls. Although devices approved through the 510(k) pathway have been shown to have higher recall rates, Class III devices are typically approved through the PMA pathway due to their higher risk classification. Based on these criteria, the **Medtronic Harmony Transcatheter Pulmonary Valve (MH-TPV) System was selected for this case study**. This device is an implantable Class III device approved through the PMA pathway, reflecting a high-risk category with strict regulatory requirements and extensive pre-market data. The device also experienced a Class I recall due to a design-related issue, aligning with the most common recall trends observed. Finally, as an implantable cardiovascular device, it has available long-term clinical data and post-market studies from multiple sources, allowing for comparison across device iterations and making it a strong case for evaluating strengths and gaps in the regulatory process.

II. Methodology

Upon a single cardiovascular device, the Medtronic Harmony PHV, being selected for this investigation, publicly available FDA data was sourced to construct a timeline of the device's approval, recall, and post-market modifications. The device's PMA record was first reviewed to identify initial approval details, including clinical trial data and post-approval requirements. This was then followed by an analysis of the FDA recall database to determine the timing, classification, and cause of the recall. After establishing this baseline, responses from both the FDA and the manufacturer were examined using FDA records, company communications, and publicly available reports. To assess how the device evolved after the recall, the FDA Total Product Life Cycle (TPLC) database, supplement records, and MDR reporting databases were then analyzed, capturing all post-approval changes, including design updates and process modifications. This analysis tracked trends in device supplements, PMA activity, and MDR reports and events over time. Data from 2021 to 2026 were extracted and organized to generate figures, with supplement purposes and device problem categories classified according to FDA-defined groupings. These updates were compared directly to the recall event to evaluate whether the underlying issue was addressed. Finally, publicly available clinical studies were reviewed to compare device performance before and after the recall, providing insight into both procedural outcomes and longer-term patient effects. Together, these sources enabled a structured evaluation of how device design, regulatory oversight, and real-world performance interact over time.

III. Results

The Medtronic Harmony Transcatheter Pulmonary Valve (MH-TPV) System is an implantable cardiovascular device that is used to replace a patient's pulmonary heart valve for pediatric and adult patients with severe pulmonary valve leakage [18] . Based on the clinical trials page from the device's FDA profile, MH-TPV had its first study record submitted on November 23, 2016, with its first version passing quality control standards a week later [19]. Afterwards, the device began its PMA approval process on November 18, 2020, and received its approval on March 26, 2021 [18]. Then, the device underwent annual progress reports submitted to the FDA. These reports included a new enrollment study with defined milestones, requiring 100% patient enrollment within 24 months [20]. They also documented a continued follow-up cohort of over 82 patients to monitor long-term outcomes. In addition, separate reports tracked a broader cohort of 150 patients across 30 sites who were not part of the original Harmony TPV study. Together, these post-approval requirements supported continued evaluation of the device's safety and effectiveness to maintain FDA approval [20]. Though no serious complications were initially reported, on March 2, 2022, Medtronic issued an Urgent Medical Device Notice to device recipients due to the risk of the capsule bond breaking during the procedure [21]. This meant there was a structural failure in the device that caused the capsule to malfunction during deployment, potentially causing harm to patients. Later, on March 24, 2022, the company issued a full recall of 1483 devices in commerce [21]. From this, the company recommended the immediate suspension of the Harmony TPV's use [21]. Of these, 665 devices were physically retrievable and subsequently recalled following six reported instances in which the bond securing the capsule to the end of the delivery catheter failed during use [22]. This recall was also reflected in other publicly available FDA data, including information on the device's supplements, total product life cycle, and related Medical Device Reporting (MDR) events and reports. [23, 24].

Using information collected from the FDA's publicly available data, **Figure 2** showcases the trends from each of these supplements, PMAs, and MDR events, from 2021 to 2025. In this, the supplements represent each time the Harmony TPV was improved or updated. The total product life cycle of PMA's represent each time a device with the same product code as the Harmony TPV was introduced or updated with a supplement. The MDRs are documented adverse events associated with any of the devices with the same product code as the Harmony [23, 24]. For a device to have the same product code as the Harmony TPV, it must perform a similar general function as the device. Across the analyzed timeframe, as shown in Figure 2, **a total of 40 supplements, 113 PMAs, and 1099 MDR reports/events were identified for the Medtronic Harmony TPV**. Through this, there was a peak in released

device supplements in 2023, at 13 supplements, which was the year right after the recall. Similarly, the total product life cycle PMAs showed a similar trend, with a small peak of 36 in 2023. However, the trend of the MDR reports and MDR events did not line up with this, since 2024 had the highest quantity, with 326, followed by 2023, with 253. Considering all this, it is important to note that the highest confirmed MDR and MDE reasons were reported to be patient-device interaction problems. As shown in **Figure 3**, this category represents the most frequently reported issue among device problems, indicating that many failures occurred during direct interaction between the device and the patient, particularly during implantation or use. Other highly reported issues, such as insufficient information and device fracture, further support that complications often arise from how the device is deployed or functions within the body rather than from isolated external factors. Furthermore, the recall issue for the Harmony TPV aligns with this category, as the capsule bond failure occurred during device–patient interaction at the time of implantation. This suggests that the failure mechanism is consistent with commonly reported MDR and MDE events, indicating that such issues are not isolated but instead reflect a broader pattern of device failures occurring during patient–device interaction, particularly during implantation or early use. [21].

Figure 4 shows the ongoing supplement purposes for the Harmony TPV from 2021 to 2026. Within this timespan, the device had a total of 50 supplements, with 45 of them being labeled as under the purpose of "process change -– manufacturer / sterilizer / packager / supplier", four being labeled as "post approval study protocol," and one being reported as "labeling change - indications/instructions/shelf life/tradename". From this, "process change -– manufacturer / sterilizer / packager / supplier" supplements include modifications to manufacturing or related procedures that may affect the safety or effectiveness of the device, while not altering its intended use or fundamental design [25]. This shows that Medtronic was consistently releasing continuous improvements to the device's safety and effectiveness even when no recall was in effect.

Although Medtronic did not have a public press release on the recall, the company opted to temporarily take the device off the market, beginning after the recall was announced and ending on February 22, 2023, reflecting the date that FDA approval was regranted [26]. Based on this date, along with the date of recall, there were seven supplements to the device during the off-market period [23]. Their corresponding changes are summarized in Figure 4 and Table 1. Furthermore, the supplement right before the date of recall was the device's post-approval study protocol received on March 11, 2022 [23]. Out of the seven supplements released for the device, only S015 directly addressed the recall reason by modifying the outer shaft manufacturing process [32].

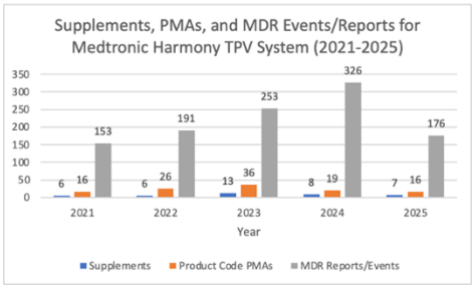

Fig. 2. Bar graph showing the trends of supplements, PMAs, and MDR events/reports from 2021-2025 for the Medtronic Harmony TPV system.

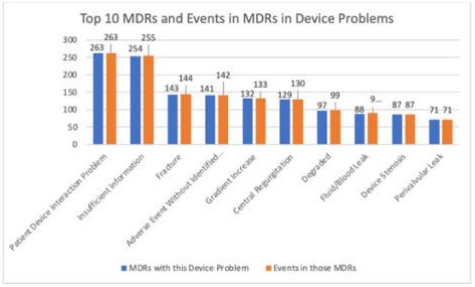

Fig. 3. Top 10 MDRs and associated events categorized by device problem for the Medtronic Harmony TPV system [24]

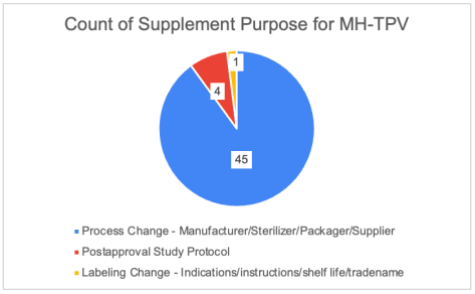

Fig. 4. Pie chart showing the number of Medtronic Harmony TPV supplements by from 2021-2026.

Additionally, the timing of supplements also makes sense, since although S014 was decided on at a later date, it was opened before S015, making this the most recently initiated supplement before the re-release of the Harmony TPV [23, 32, 33]. This means that Medtronic planned to re-release the device once S015 was determined to have addressed the issue, highlighting the 11-month gap between the official recall date and the S015 decision date [32] [21]. However, it is important to note that there is currently no publicly available information regarding the specific process Medtronic followed to fix the issue aside from the fact that Medtronic worked closely with the FDA to earn reapproval [34].

TABLE I.
Summary of Medtronic Harmony TPV System PMA Supplements Implemented During Off-Market Period (2022–2023) [27 - 33]

Supplement ID	Decision Date	Type of Supplement	Description of Change
S0009	May 23, 2022	30 Day Notice: Process Change – Manufacturer / Sterilizer / Packager / Supplier	Reduction in solution volume during tissue fixation
S011	July 27, 2022		Increase in the timeframe for receipt of porcine pericardial tissue from abattoirs and initiation of tissue fixation
S010	Aug. 8, 2022		Re-validation of an existing cleanroom
S012	Nov. 1, 2022		Automation of a verification step undertaken by Sterile Release Personnel (SRP) for Limulus amebocyte lysate (LAL) Bacterial Endotoxin Testing (BET) prior to final release of product
S013	Dec. 1, 2022		Implement an alternative bacterial water testing method
S015	Feb. 12, 2023		Various modifications to the Harmony Delivery Catheter System (DCS) outer shaft subassembly manufacturing process
S014	Feb. 15, 2023		Introduce the Optimized PCA Sterilization Cycle for sterilization of the Harmony delivery catheter and loading systems

While regulatory actions and device improvements were ongoing, some patients continued using the earlier version of the device, as 818 units were already implanted and not retrieved from circulation after the recall. A 24-month study on the Harmony TPV reported that the "Harmony valve demonstrated excellent clinical and hemodynamic outcomes through more than one year of follow-up" [35]. Notably, this study included patients treated before and shortly after the recall, using data from eleven U.S. centers through April 30, 2022, a period between the recall and the device's reintroduction to the market [35]. Together, these findings suggest that the device's issues were primarily limited to the implantation phase rather than long-term performance.

IV. Discussions and Conclusions

Despite strict regulatory oversight, the persistence of design-related recalls in high-risk cardiovascular devices reveals key gaps in pre-market evaluation and testing processes. Even though the PMA pathway is considered the more rigorous pathway compared to the 510(k) pathway, it still does not prevent major failures. Furthermore, because the MH-TPV recall involved a Class III, PMA-approved Medtronic device with a primary design-related failure, this raises the need for further investigation into whether similar vulnerabilities exist across other high-risk devices and to what extent the PMA pathway prevents design-related failures from reaching patients. Additionally, the nature of the MH-TPV failure is important to understanding where PMA evaluation does not account for all risks. First, the recall stemmed from a structural bond within the delivery catheter breaking during the deployment procedure itself, not during long-term use. This is important, since it shows that despite the current pre-market standards in place, a core structural issue was not discovered. It is not clear if PMA clinical trials are conducted under conditions that fully replicate the mechanical stresses of real-world implantation. For the MH-TPV, the six documented bond failures showed that the original trial population pre-market may not have been large or diverse enough to expose the system to enough test cases. Furthermore, the approximately one-year gap between the MH-TPV's approval in March 2021 and its recall in March 2022 further illustrates this limitation. Rather than indicating a failure of post-market surveillance alone, this gap likely reflects the reality that certain procedure-dependent failures do not happen during every situation, meaning that they may only become detectable once a device has been implanted across a sufficiently large and varied patient population. It is important to note that once the failure was identified, Medtronic issued an urgent medical device notice and initiated a full recall within weeks, showing a regulated recall process. However, the current structure, in which clinical trial populations can be limited, may create a window where rare but serious implantation-specific failures go undetected until post-market use reaches a critical volume. The supplement timeline following the recall demonstrates both the responsiveness and the complexity of the regulatory correction process. Of the seven supplements submitted during the off-market period between March 2022 and February 2023, only S015 directly addressed the recall reason by modifying the outer shaft manufacturing process of the delivery catheter [32]. The preceding six supplements covered adjacent process improvements, including changes to tissue fixation protocols, cleanroom revalidation, and updated sterilization cycles [27-33]. This pattern suggests that Medtronic used the off-market period not only to fix the identified failure but to conduct a broader manufacturing review, which aligns with the spike in supplement activity visible in 2023 relative to all other years. The timing of S015 as the final supplement before FDA reapproval on February 22, 2023 further supports this, indicating that Medtronic planned reintroduction around the resolution of that specific issue.

However, the analysis highlights an unresolved question. MDR reports and events reached their highest levels in 2024—after the device returned to the market—rather than in 2023, when regulatory corrections were most active. The most commonly reported MDR issue was patient–device interaction problems, which is consistent with the bond failure mechanism identified in the original recall. [24]. Whether this 2024 peak reflects events from the 818 units never retrieved from commerce, reports generated by the updated device's broader deployment, or a lag in MDR reporting timelines cannot be determined from publicly available data alone. This gap in transparency is a broader limitation of the recall resolution process. While Medtronic confirmed it worked closely with the FDA to earn reapproval, no public documentation details the specific engineering process used to resolve the bond failure [34]. This limits the ability of other manufacturers and researchers to learn from the failure and apply those lessons to analogous devices. Taken together, these findings suggest that while the regulatory system functions as a continuous cycle of monitoring and iterative refinement, it relies on real-world deployment to surface certain categories of failure that controlled pre-market

testing cannot fully anticipate. The MH-TPV case specifically points to implantation-stage mechanical stress as an underexamined risk domain within PMA evaluation. Future regulatory improvements could focus on standardizing deployment-stress simulation protocols during pre-market testing, or requiring larger and more anatomically diverse trial populations for implantable devices. While these changes would not eliminate post-market risk, they could narrow the window between approval and the identification of critical design failures, reducing the number of patients exposed before corrective action is taken.

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