

An Oracle White Paper
October 2010

Delivering Innovation in the Medical Device Industry

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Product Innovation Approval Process

Product Innovation is a key performance indicator (KPI) for the medical device industry. Faster time-to-market and ongoing regulatory compliance are two key value drivers for successful product launches. However, due to the highly regulated nature of this industry, companies face a regulatory process that is lengthy and unpredictable and can delay product launches impacting company profitability. Medical device companies must focus on a comprehensive product innovation process that enables FDA compliant datasets to meet regulatory approval and compliance requirements and shortens NPD cycle time.

The FDA has classified three types of medical devices:

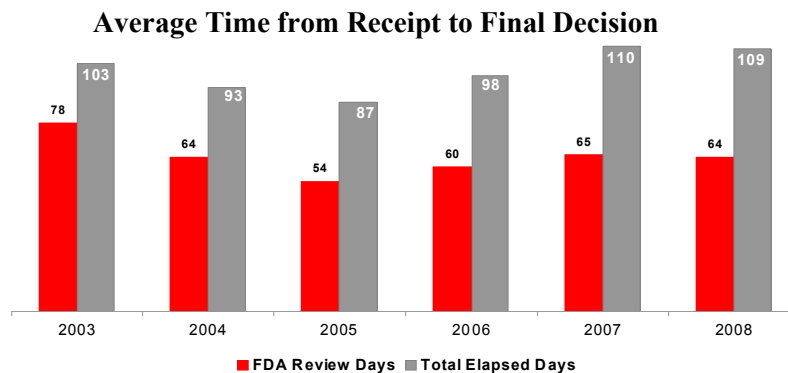
- **Class I** devices are generally exempt from premarket notification requirements and are subject to general controls
- **Class II** devices have requirements/controls such as labeling, mandatory performance standards, and post-market surveillance. The category of products are cleared via a premarket notification, or 510(K) submission process
- **Class III** devices must seek FDA approval via a premarket approval (PMA) process

Faster Time-to-Market

Any medical device company driving new product innovation or changes to existing products in either Class II or Class III categories of products needs to undergo the FDA review process to evaluate the efficacy and product safety.

Class II approval

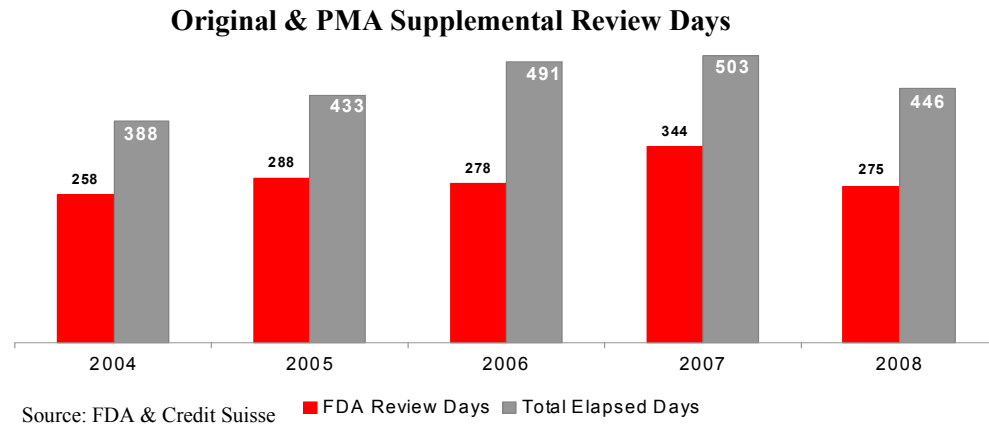
The 510 (k) approval process for the Class II type device usually takes about 90 days. As part of the approval process, the applicant must demonstrate that the device being submitted for FDA approval is either (1) substantially equivalent and has the same technological characteristics as the predicate, or (2) used for the same intended purpose as the predicate, has different technological characteristics as the predicate, but is as effective and as safe as the predicate.



Source: FDA

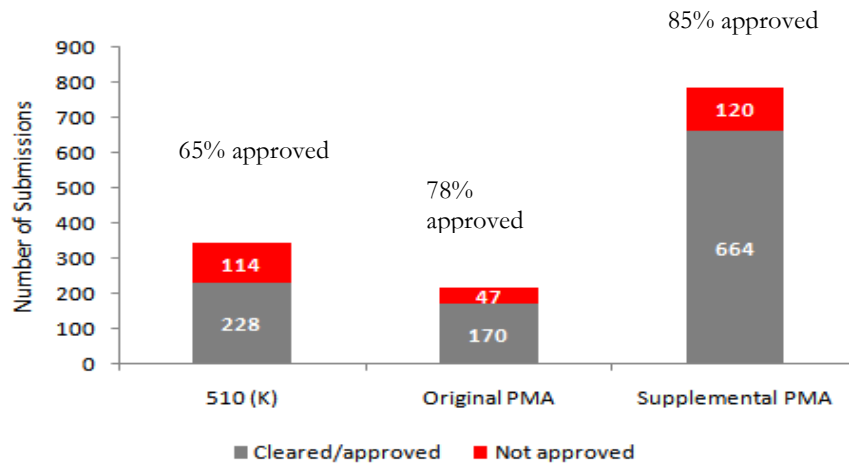
Class III approval

Premarket approval (PMA) is the FDA review process to evaluate complexity and risks associated with Class III devices. The regulatory review process for market approval for Class III devices is more extensive than Class II devices. Under FDA regulations, the agency has up to 180 days to review and grant approval. After the FDA makes a decision, interested parties may petition it within 30 days.



In January 2009, the US Government Accountability Office (GAO) studied FDA data from fiscal 2003-2007 as it relates to Class I, Class II and Class III devices.

FDA Review Decisions in FY2003-2007 by FDA Review and Decision



Source: GAO analysis of FDA data, Credit Suisse

The GAO analysis of FDA data indicates that companies planning to launch new products in Class II or Class III categories have a significant probability of being denied FDA approval. Over the five year period, the Class II category had a 65% approval rate vs. 78% for the Class III category device. This delay or denial is in addition to elapsed time (446 days for Class III and 109 for Class II) from the day of filing. It is imperative for medical device companies to enable a closed-loop collaborative (external and internal) environment to manage all aspects of product development and the necessary infrastructure required to meet the regulatory compliance requirements before making submissions for FDA approval.

Regulatory Compliance

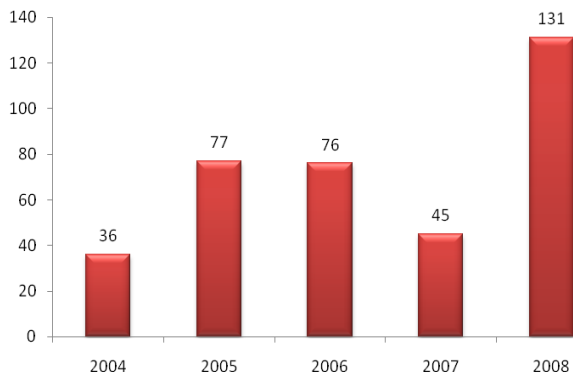
The office of Regulatory Affairs (ORA) is primarily responsible for conducting domestic and foreign inspections, collection, and analysis of samples.

FDA Enforcement Activities - 2008

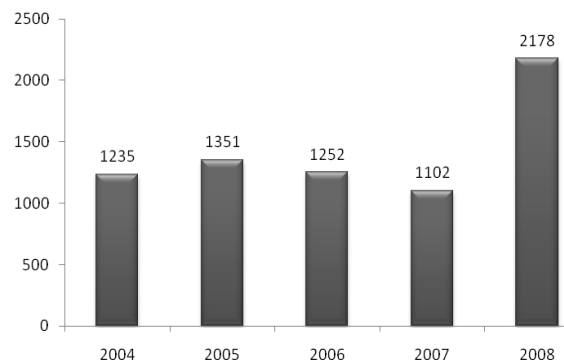
Seizures	8
Injunctions	5
Convictions - OCI	369
Warning letters	445
Recall events	2,721
FDA 483s Issues	4,987
Inspections	15,245
Import Refusals	17,907
Fines/Restitutions	\$846,591,090

Source: FDA

The FDA has three classes of recalls and Class I is considered to be the highest risk. Class II recalls may cause temporary or medically reversible adverse consequences in which the probability of serious adverse health consequences is remote.



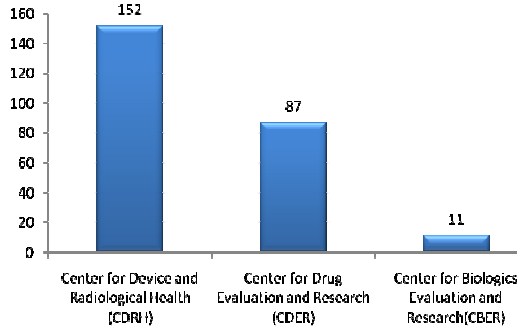
Class I Recalls – CDRH



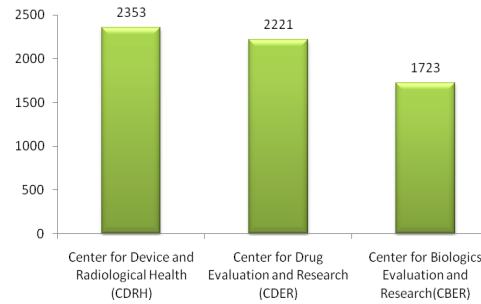
Class II Recalls – CDRH

Source: FDA & Credit Suisse

In addition, the FDA may issue warning letters to a device manufacturer for a number of reasons, including but not limited to violation of good manufacturing practices and quality system regulations.



Warning Letters, Fiscal 2008



Inspections by FDA, 2008

Source: FDA, & Credit Suisse

Hence, it is very critical for medical device companies to leverage a closed-loop enterprise quality process across all key stakeholders of the product (R&D, Operations, Quality, Service, Support, etc.) to minimize any delays in producing compliant datasets and documentation for FDA approval and ongoing compliance. Quality should be at the forefront of the product innovation process and not an afterthought to minimize any financial exposure and liability.

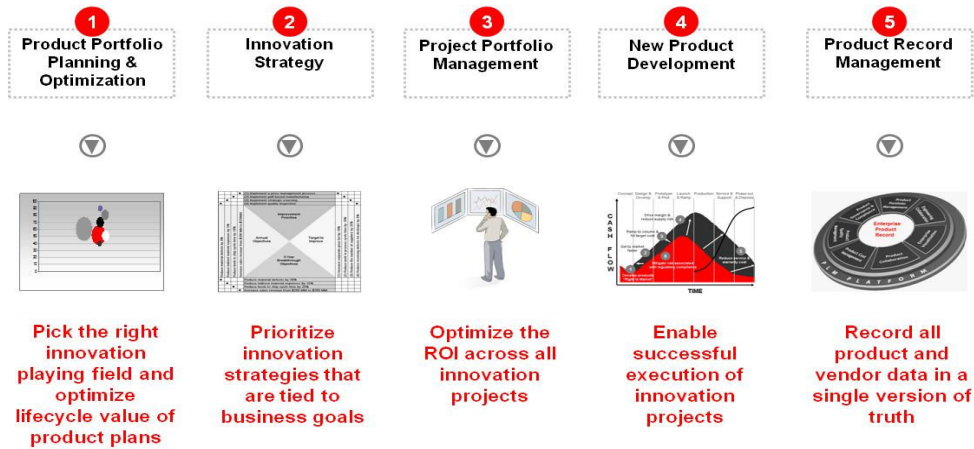
Developing a PLM Strategy

In summary, medical device companies should have a comprehensive product lifecycle management (PLM) strategy delivering growth and product innovation. Lack of a comprehensive PLM approach can potentially impact profitability with delayed and costly product launches.



Product Cash flow curve for delayed product launch

Oracle recommends a closed-loop Innovation framework based on 5 key pillars that integrates innovation strategy and execution for the medical device industry.



Oracle’s Product Innovation Framework

- Optimize corporate ROI with effective **Product Portfolio Planning & Optimization**.
- Develop **Innovation Strategies** tied to business goals.
- Monitor and measure development projects with effective **Project Portfolio Management**.
- Enable successful execution with disciplined **New Product Development Process**.
- Enhance enterprise collaboration capabilities with effective **Product Record Management**.

This framework enables medical device companies to manage product innovation by leveraging a compliant dataset, a key requirement for FDA approval, across the enterprise to mitigate any regulatory compliance violations and produce all necessary data and documentation to avoid any delays in the FDA approval process. The benefits of investing in a robust innovation process that spans the spectrum of activities from strategic to execution-oriented are extremely compelling.

Figure below shows the improvement opportunities along a few key innovation metrics aligned to the key pillars of the framework.



How Can Oracle Help?

Innovation is a process that concerns top management at all levels of the corporation. The CEO, CFO, V.P. of Corporate Strategy, V.P. Engineering, V.P. Purchasing, and V.P. Quality must all be involved in assessing the maturity of their organization's innovation capability.

Oracle Insight Program

Oracle Insight uses a proven methodology, which is flexible and customized to individual company objectives. Most engagements consist of four steps: Industry Perspective, Discovery, Solution Design, and Solution Presentation.

Industry Perspective

Given the plethora of acquisitions made by Oracle, we want to help you understand how these new capabilities have helped others in your industry. Oracle facilitates an in-depth discussion with your executives about industry trends, best practices, vision, strategy, challenges, and roadblocks.

Discovery

Leveraging established industry frameworks and robust intellectual property, Oracle Insight collaborates with you to assess your current business processes and identify the capabilities required to achieve your corporate strategy.

Solution Design

Oracle recommends best practice processes and supporting technology, including a time-to-benefit analysis and implementation plan.

Solution Presentation

The Insight team works with you to create an executive presentation including supporting information, business benefits, and value drivers, to help you build consensus among colleagues and executive management or secure funding from your board.

Oracle Insight engagements are flexible. Once executive commitment is secured, the program will be customized to your needs and objectives as it relates to your project.



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