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MARKETING AUTHORIZATION APPROVAL FOR MEDICAL DEVICES IN US

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ABSTRACT

From the proof-of-concept to the commercialization phases, developing a one-of-a-kind healthcare product (medical device) is an expensive and time-consuming endeavor. It will take several years of study and development. Product development processes should be carried out in compliance with appropriate regulatory requirements to save time and money when bringing items to market. These specifications can assist you in staying current with your development efforts and producing a product that fulfills the regulatory standards of your target jurisdiction(s), i.e., a high-quality product that is harmless and actual for its proposed application. Despite fact that information on regulatory requirements for healthcare product development is generally available (e.g., law, guidance documents, international standards), navigating the regulatory system is difficult, especially when dealing with different nations. To help entrepreneurs who are developing healthcare products.

The major goal is to improve regulatory understanding of product development and assure regulatory compliance. It could serve as a starting point for the development of your product. The book, rather than a compendium of regulations, covers the key concepts and principles in regulatory affairs.

Keywords: Medical Devices, Proof-of-Concept, Regulatory Compliance, Premarket Approval (PMA), Post-Market Surveillance

INTRODUCTION

The US Food and Drug Administration classifies materials used for surgical dressings, bandages, staples, sutures, ligatures, and blood and blood component collecting bags with or without anticoagulant as medical devices. Examples of mechanical contraception include pesticides, disinfectants, and contraceptive methods (condoms, IUDs, tubal rings) that are frequently advised against.

Medical device" is defined as "devices intended for internal or external use in the diagnosis, treatment, mitigation, or prevention of disease or disorder in humans or animals."**[1]**

Examples of Medical Devices:

Elastic Bandages

Bone fixation screw

Piston syringe

Classifications of Medical Devices according to the U.S. FDA are as follows:[2]

Based on the features, possible applications, and inherent dangers of the devices, the FDA classifies medical devices into three risk classes.

Table 1: Classification of Medical Devices in US

Sl No.	Class	Risk Based	Examples
01	Class I	Low Risk	Elastic bandages, Examination Glove, Adult Incontinence Pad
02	Class II	Medium Risk	Infusion Pumps, Bone fixation screw, Blood pressure Kit
03	Class III	High Risk	Pacemakers, Dental Lasers, Heart Valves

MEDICAL DEVICE RULES:

Enforcing rules is the responsibility of the Food and Drug Administration (FDA) to guarantee the protection and effectiveness of medical devices in the US. This program is overseen by the Center for Devices and Radiological Health (CDRH) at the FDA.

There are three risk classes for medical equipment: Class I, Class II, and Class III. Class I devices are the harmless, and class III devices are the deadliest. Therefore, governing inspections are applicable to equipment that is categorized as Class I through Class III.

While most Class II devices are required to comply, the common of Class I devices are exempt from the 510(k) premarket notice requirement. Class III devices must still submit a Premarket Approval Application (PMA) to the FDA even though they are exempt from notification requirements **[2]**.

Types of FDA Regulations for Medical Devices:[3]

Table 2: Regulations for Medical Devices in US

Sl No.	Title of the Regulation	CFR Belongs too
1.	Establishment Registration & Medical Device Listing	21 CFR Part 807
2.	Premarket Notification 510(k)	21 CFR Part 807 Subpart E
3.	Premarket Approval (PMA)	21 CFR Part 814
4.	Investigational Device Exemption (IDE) for clinical studies	21CFR Part 812
5.	Quality System (QS) regulation	21 CFR Part 820
6.	Labelling requirements	21 CFR Part 801
7.	Medical Device Reporting (MDR	21 CFR Part 803

Guidance Documents: [4]

Table 3: Guidance Documents for Medical Devices in US

Sl No.	Guidance Documents
1.	Covid-19 Related Documents
2.	Product-Specific Guidance for Generic Drug Development
3.	Clinical Trials Guidance Documents
4.	Guidance For Industry and Food and Drug Administration Staff
5.	Premarket Notification - Guidance for Industry and FDA Staff

RESULTS & DISCUSSIONS:

Investigational Device Exemption (IDE):

An IDE request may be issued in order to obtain data regarding an investigational device's efficacy and safety prior to using it in clinical trials. A PMA is typically maintained by clinical research. Clinical data are rarely required for 510(k) applications. Clinical trials of legally marketed medications with novel intended applications are also examples of experimental usage. Every clinical trial involving investigational devices, unless otherwise stated, must commence with an authorized IDE **[5]**

Bone fixation

Examination Glove

Infusion Pumps

Devices not yet authorized for commercial use must undergo clinical testing:[5]

- A study plan that has been given institutional review board (IRB) consent. The FDA has to added approve the IDE if the research includes a major risk device;
- Every knowledgeable patient's consent;
- A warning notice indicating that the gadget is meant only for academic purposes;
- Observation of the research and;
- Necessary documentation and reporting.

Medical device Regulation:[6]

Table 4: Regulations of medical devices in us

Sl No.	CFR	Brief about regulation
01.	21 CFR 812	Investigational Device Exemptions - covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities of sponsors and investigators, labelling, records, and reports.
	21 CFR 812.1	Investigational Device Exemptions – General Provision - Scope
	21 CFR 812.3	Investigational Device Exemptions – General Provision – Definitions

Premarket Notification 510(K):

In compliance with FD&C Act section 513(i)(1)(A), the FDA certifies through a 510(k) application that the provided device is equally harmless and active as one that is sold legally. Anyone wishing to market a Class I, II, or III device intended for human use in the United States must file a 510(k) with FDA unless the device is exempt from the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and does not exceed the limitations of exemptions in.9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). Although no 510(k) form exists, the filing processes are outlined in 21 CFR 807 Subpart E. Each submitter must get a letter from the FDA certifying that their product is substantially similar (SE) before marketing it. This demonstrates that the device is commercially viable in the US. This order "clears" apparatus in anticipation of an open market sale.

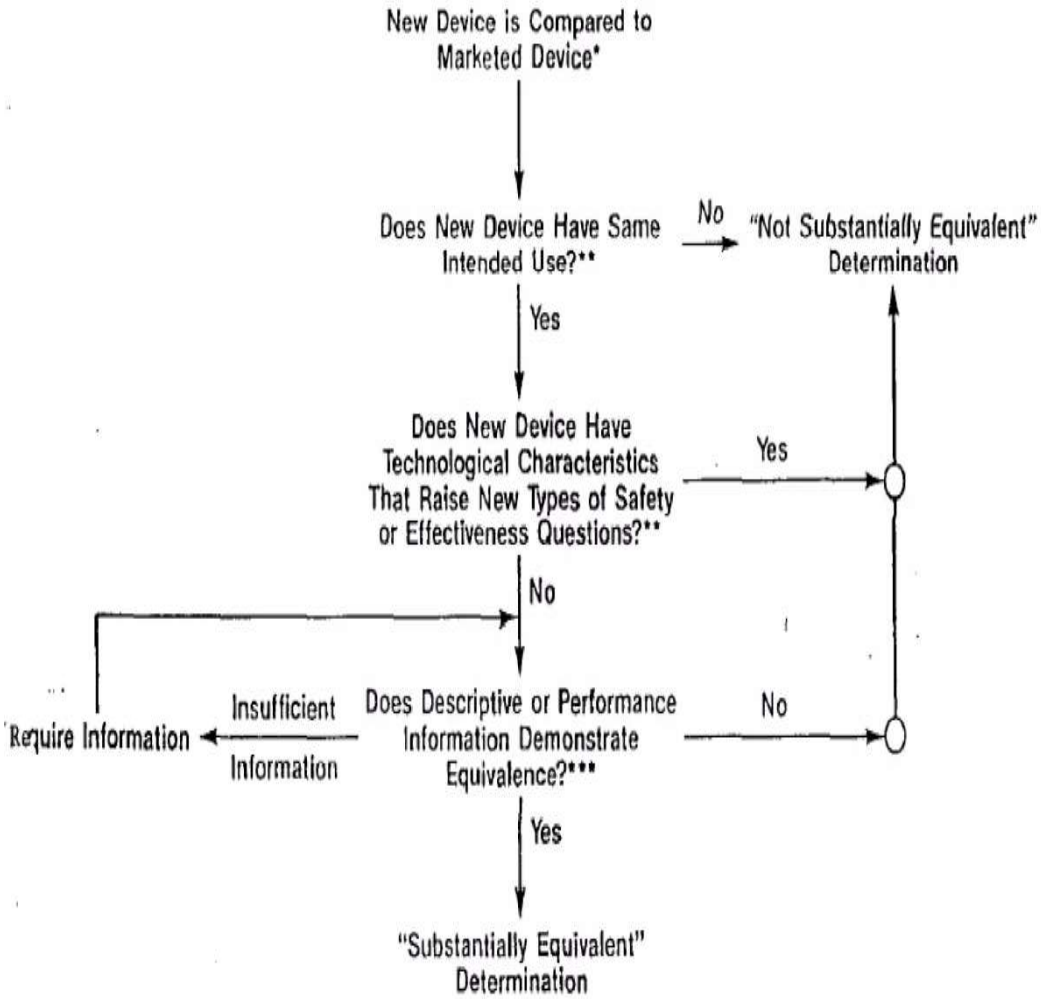


Figure 1: 510(K) Approval Process for Medical Devices in US

What is Substantial Equivalence:

Evidence that a product is substantially equivalent to another legally marketed product in the US is needed for a 510(k) filing. "Substantial equivalence" means that the protection and effectiveness of the new gadget are comparable to those of the old one.

In the event where a device and a predicate are almost identical, then:

- achieves the purpose anticipated by the predicate.; **and**
- has many of the technological characteristics of the predicate; **or**
- has exclusive technological properties and doesn't endanger efficacy or safety; **and**
- Evidence indicating the device is just as safe and efficient as the one that is sold lawfully was submitted to the FDA.

Who's required to submit 510(K):

- Domestic manufacturers
- Specification developers
- updated labels whose actions have a major impact on the device.

When 510(K) is required

Something that was lawfully purchased has been altered or tampered with, endangering its usefulness or security. The justification for filing a new 510(k) should be included in the change control paperwork.

When a 510(K) is not required:

- Components can be sold to other businesses so they can be utilized to make gadgets, or incomplete goods can be sold to another business for additional processing. If your components are going to be shipped as replacement parts straight to customers, you have to file a 510(k).
- Your devices not publicly advertised or distributed. No 510(k) clearance is necessary to manufacture, or test a device.
- You market a product manufactured in the United States by another company. If the device is labelled "Distributed by ABC Firm" or "Manufactured for ABC Firm," no 510(k) (21 CFR 801.1) filing is required.
- Your product is not subject to 21 CFR 862–892, the 510(k) rules. Stated differently, some Class I or II devices may be made available for sale without a 510(k). The GMP guidelines and 510(k) specify how Class I and II exempt medical equipment devices are to be dispensed with.

Preamendments Devices:

"Preamble's device" describes products that a business sold in the US legally before May 28, 1976, but have not since been:

- altered or changed considerably since then; and

- As of right now, the FDA has not issued any regulations requiring a PMA application.

Electronic devices that satisfy the aforementioned criteria are considered "grandfathered" and are not subject to the 510(k) restrictions. The apparatus needs to operate precisely as it did on May 28, 1976. For a device labelled for a new purpose to be approved for marketing, the FDA must receive a 510(k) form. We refer to this kind of gadget as a new device **[7]**.

Pre-Market Approval Program, or PMA:

Before being put on sale, any medical device that presents a significant risk must be approved, such as the Class III medical devices I mentioned before. A PMA is required if the regulation or classification in the CFR requires one.

Purpose of the PMA:

In addition, the PMA seeks to show the FDA that the device is a workable and fairly safe instrument in and of itself, supported by credible scientific data**. As a result, while the 510(k) is effectively a "me too" to the reference device**, the PMA device stands on its own due to considerable clinical research **[8]**.

Approval Process for US: [9]

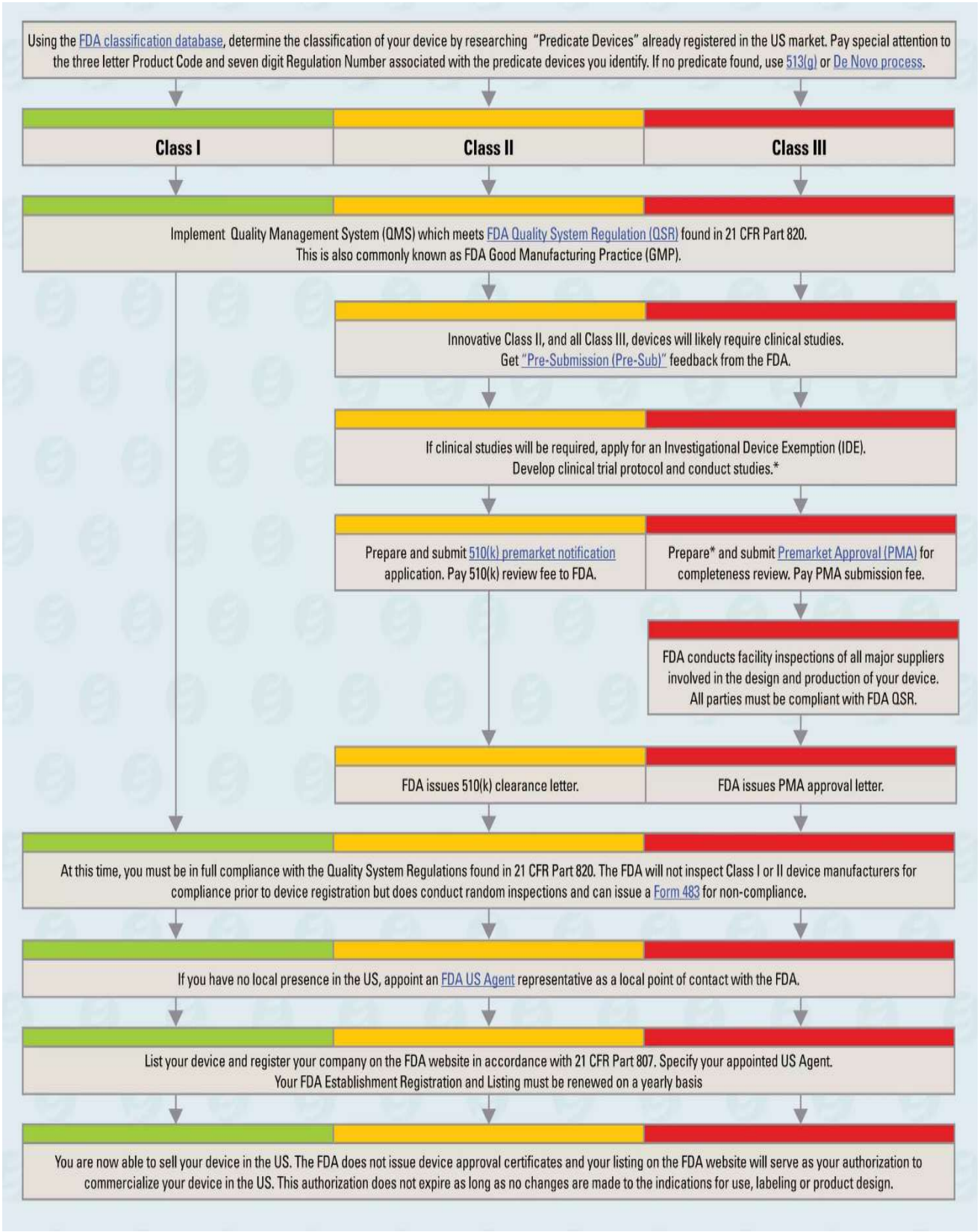
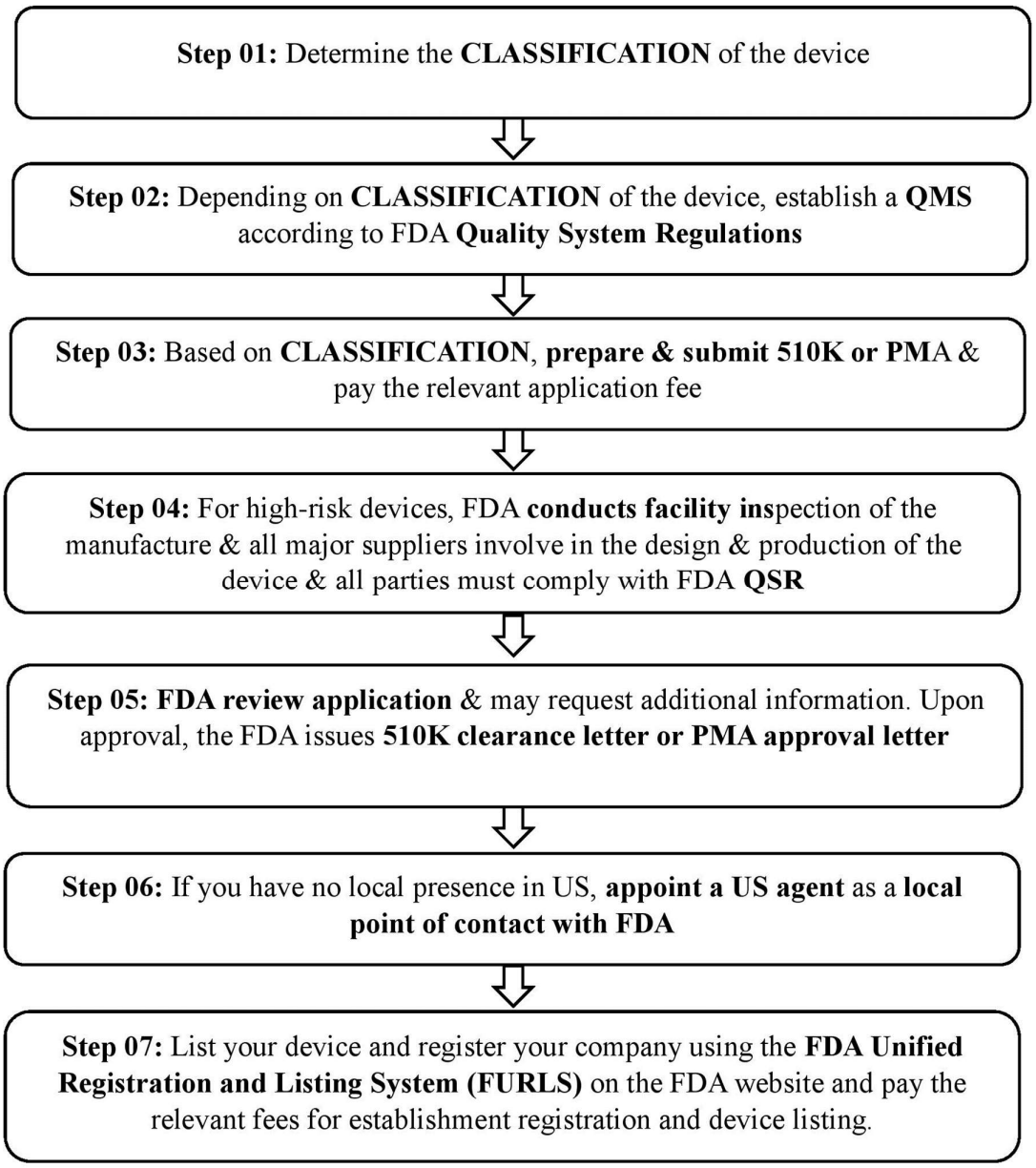


Figure 2: Approval Process flowchart for medical devices in US

Overview: US FDA medical and IVD device approval process: [10]



Timelines:[10]

Table 5: Timelines frame of medical devices in US

Sl No.	Class	Timelines frame
1.	Class I (Low Risk)	30 – 90 Days
2.	Class II (Medium Risk)	1 – 9 Months (510k)
3.	Class III (High Risk)	9 – 36 Months (PMA Approval)

CONCLUSION:

The current study provides a detailed **regulatory information** of act/regulations and guidelines for **Medical Devices in US**. Obtaining marketing authorization for medical devices in the US is a time-consuming process that entails going through numerous regulatory channels based on the product's risk assessment. To assurance that devices full fill stringent **safety and efficacy** standards, manufacturers and the FDA must work together.

To be in compliance, manufacturers must keep track of regulatory updates and react to changing requirements. Furthermore, the FDA promotes early collaboration with the agency through **pre-submission meetings** and other procedures to aid in the **regulatory process.**

Stakeholders in the medical device sector should check the FDA's official website and other reliable sources on a frequent basis for the most conversant information on governing standards and procedures. Consult with regulatory specialists and legal professionals who are knowledgeable with medical device approvals to help you in understanding information related to different types of **Applications for Medical Devices in US (IDE, 510K & PMA**) and **ensure a successful marketing authorization.**

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CONFLICT OF INTEREST:

The authors declared that there is no conflict of interest

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