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REGULATIONS OF MEDICAL DEVICE IN USA

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Abstract:

Regulations of medical device plays a very significant role in designing, development and commercializing new medical device and their technologies. Understanding complete regulatory requirements for a medical device will show us essential successful results in innovation. In this article we review about the medical device regulations, classifications and regulatory requirements in United States market. Risk-based classification of medical device is essential for the determination of the medical device regulatory pathway which was implemented by United States Food and Drug Administration (USFDA). At the early stages of development of medical devices we should be cautious about the analysis and consideration significant in the different pathways. Another important aspect of medical device regulation is to outline the specific requirements for testing, production, development and postmarketing surveillance specified by FDA's QSR (Quality System Regulation). To ensure that the marketed device is safe and effective FDA present its relationship and elements to control the design and operating procedures involved in the manufacturing process. Recent implementations by the USFDA on combination products (combining biologics with devices or drugs with devices) allows for adequate regulations for review purpose.

Keywords: *PMA, FDA, CDHR, 510(K) process, FD&C,IMDRF, GHTF, IDE, QSR, QMS*

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INTRODUCTION:

Medical device is defined as any apparatus, software, instrument, material, article or appliance used in combination or alone, including the software process intended by its manufacturer to be used specifically for therapeutic purpose and/or diagnostic, proposed by the manufacturer to be used for the sake of human beings for the purpose of treatment, diagnosis, alleviation, monitoring, prevention and replacement, modification, investigation of the physiological process or anatomy. One can save lives from the Medical device sector by providing pioneer and innovative healthcare ideas about prevention, diagnosis, alleviation, treatment and monitoring. Examples include from simple range of devices like medical thermometers, tongue depressors, disposable gloves to sophisticated devices like prostheses, implants and computers associated with medical testing.

Medical Device Significance

Mortality and morbidity of life is decreased due to this era consisting of newer technology and development. Development in the medical field in terms of medical devices and drugs has bought a vigorous change in the people's life (cardiology devices, treatment for face, dentist and cosmetic). The ability of the physicians has extended by medical devices to treat and diagnose diseases and make necessary contribution to get a quality and healthy life.

Medical Device Regulations according to WHO (World Health Organisation), Geneva, the term 'Medical Devices' includes everything from a simple wooden tongue depressor to a highly sophisticated computerized medical equipment. The medical device chief mode of action is in contrast on the human body with that of medicinal products, it is not pharmacologic, immunologic or metabolic. A wide range of products are included under medical devices such as bandages, gloves, condoms, syringes, disinfectants, contact lenses, surgical lasers, X-ray equipment, dialysis equipment, pacemakers, heart valves and baby incubators. Medical devices is any apparatus, instrument, appliance, machine, *in vitro* reagent or calibrator, implant, material, similar or related articles, materials, proposed by the manufacturer to use in combination or alone, for human beings for one or more specific purposes like prevention, diagnosis, alleviation or treatment, monitoring of diseases; treatment, monitoring, diagnosis, compensation or alleviation of an injury; replacement, investigation, support or modification of the anatomy of a physiological process; control of contraception; sustaining or supporting life; disinfection of devices and providing data for medical purposes by performing in vitro examination of specimens which are derives from the human body. [2]

Medical devices are now considered as a prevalent part of modern medical care. Almost in all cases its always associated with essential quality of care. There are cases where quality was improved by the use of medical devices. Regulations plays a major role to establish qualitative aspects in medical devices. Since 85% of manufacture of medical devices is carried out in the USA, in European Union countries and in Japan, strict and concerns are very important. [2]

Like health technologies and medicines, they are very essential for public care at the bedside, also at the countryside health clinics or even at the specialized hospitals. There is a double-digit growth of medical devices in the market. 20% is the growth rate of cardiac devices alone in the market. In India, 10-15% is the rate of growth of market. Thus, this is a clear indication showing the growth rate is at high levels in our country. This growth is because of improved awareness about health care, patient's affordability, number of disease patterns and upgraded hospital infrastructure. [3]

Medical Device Classification

Medical Devices are classified according to the manufacturing aspects, technical design and medical utility. Moreover, all the regulatory authorities in the world classified based on quality standards and safety requirements. Numerous criteria are set to evaluate duration of contact, degree of invasiveness, systemic verses local effects and affected body system. Classification of medical device varies from country to country.

Table 1 given below shows comprehensive view of medical devices classes according to United States. [4]

Category	Explanation
Class I	Class I medical devices are excused from clearance, they are subjected to the requirements under general control.
Class II	For Class I and Class II medical devices marketing clearance 510 (k) is essential. To obtain this clearance it is compulsory for the manufacturer to submit data showing the equivalent activities as that of existing device in the American market.
Class III	Stringent procedures are followed to get a marketing clearance for Class III medical devices [stricter 510 (k), PMA (Pre-Market Approval) or PDP (Product Development Protocol)]

Medical Device regulations in USA

The standards (or norms, or regulations) are projected to protect the public against the risk associated with manufacture, design and packaging of Medical Devices. These regulations are different from one country to another.

Regulatory agency USFDA is responsible for ensuring medical device to be safe and effective. It's an immense universe having different types of medical device which can be approximately 5,000 encompassing from microbiology to microelectronics. Product development is regulated by FDA's CDRH (Center for Devices and Radiological Health). 21 CFR 820 (Quality System Regulation) regulates the quality assurance and manufacture of medical devices in United States and publicly accessible audit reports. Regulations in US came in 1978 that is 20 years earlier than the European Union. USFDA registers the devices and manufacturers are authorised to market the product in USA. The competence level in the US in very high hence sanctions are impossible if they found non-compliance in the inspection.

Medical device can be bought into market by any one of the given 7 pathways below:

- Pre-market approval (PMA)
- De novo process
- 510 (k) also known as Pre-market notification
- CDE or Customer Device Exemption
- PDP or Product Development Protocol
- Expanded access option and
- HDE or Humanitarian Device Exemption [4, 5]
-

90% of the medical device are brought into US market by Pre-market notification method, 5% by Pre-market approval process and 5% are brought by the remaining 5 pathways. According to 2017 update it costs around $5000-$15000 for Class I medical device, $15000-$30000 for Class I and Class II medical device and $30000-$50000 for Class III medical devices. [6, 7] Brief pathway or medical device registration is shown in Figure 1

Registration of medical devices in a brief pathway:

- **Pre-market approval (PMA)**

PMA is a FDA's regulatory and scientific review department to assess the safety and effectiveness of high risk medical devices (Class III). If a new device is substantially different than that of existing device then it is necessary to undergo PMA process. Class III medical devices are also called as High-risk class since it is associated with risks. Under FD & C act section 515 is required to be followed for PMA application to prove the safety and efficacy of the Class III medical device since special and general controls are not sufficient. Clinical study is also a necessary document to be submitted to the FDA to prove efficacy and safety. It requires 180 days for a PMA to be approved by the FDA. [8]

- **510 (k) or Pre-market notification**

Pre-market notification is an assurance for safety and efficacy of the medical device given to the FDA to market the device. If the medical device is substantially equivalent to the existed marketed device then 510 (k) process is followed. New device having same technological features and same intended use as that of the predicted device then it is known as Substantially equivalent. Pre-market notification is required when;

- Introducing a new device for the first time after 1976 into the commercial distribution.
- The device which is commercially distributed but having different intended use.
- Modifications or changes of a legally marketed medical device which affects the safety and effectiveness of the device. 510 (k) process for market clearance is given by FDA. FDA takes almost 30 to 90 days to give clearance for a device.

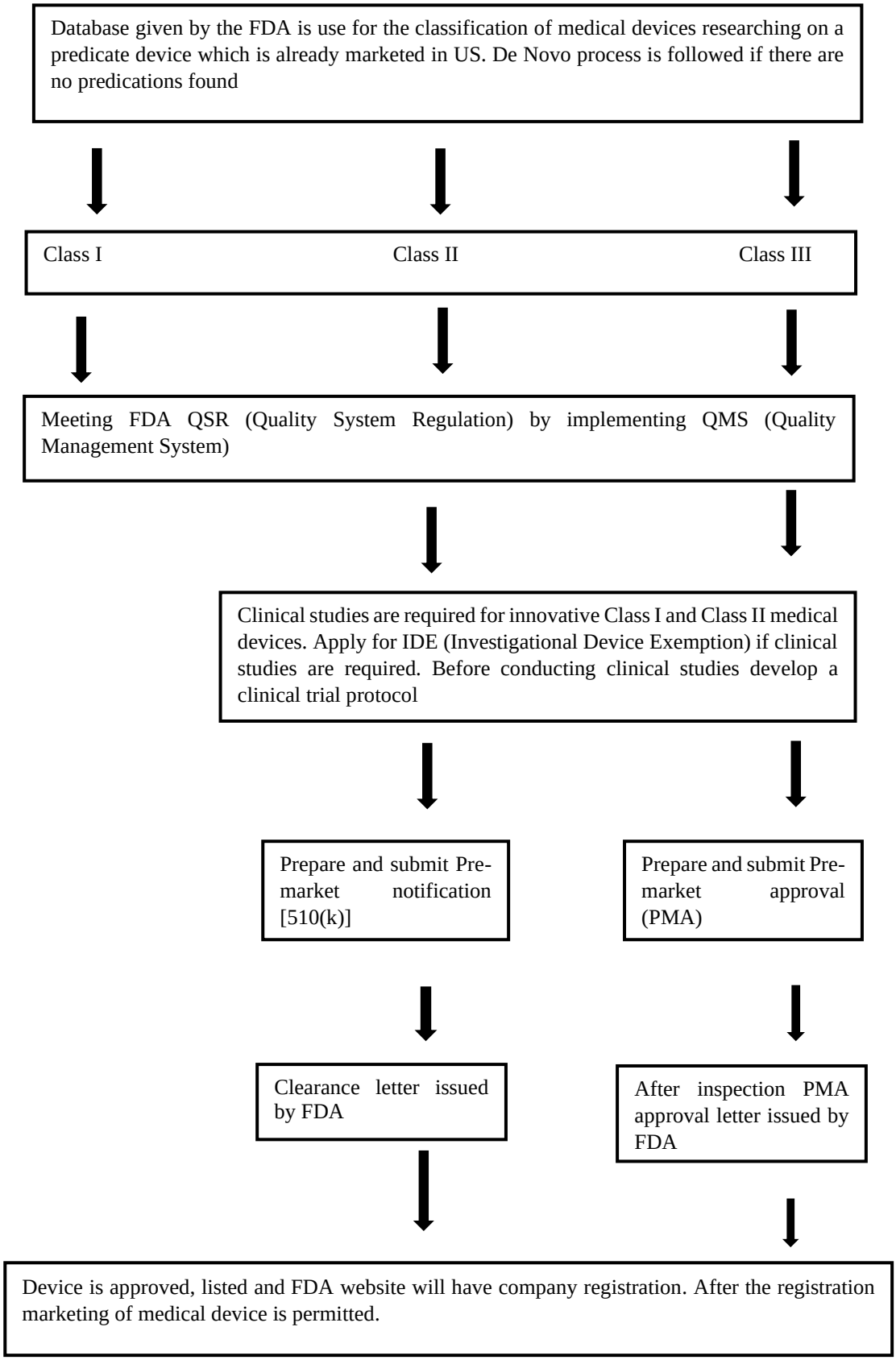

Figure 1: Registration process of Medical Device in USA

- **De Novo Process**

To market a device in a faster way this process can be followed. New type medical devices not previously classified on the basis of risk by FDA will be automatically considered under Class III according to the FD&C section 513 (f)(1). New category devices with no high risk are reviewed by FDA.

Confirmation is based on two criteria:

1. Medical devices should be under low to moderate risk and should also comply with the standards for Class I and Class II devices that is under FD&C Act section 513(a)(1).
2. New device ratio of benefit and risk must be understandable. It should be under Special and General control. FDA accepts the De Novo request and classifies in Class I and Class II if criteria are met. Using the De Novo medical device future medical devices can get market clearance through Pre-market notification process showing Substantial equivalent with the De Novo as 'predicate'. [9,10]

Regulations Harmonization for Medical Devices

A voluntary group of regulators for medical device from all over the world have gathered together to construct a strong foundation work called IMDRF (International Medical Device Regulators Forum). Previously IMDRF was known as GHTF (Global Harmonization Task Force). [11]

Harmonization benefits

- Ensure the quality, performance, safety and effectiveness of the Medical Device.
- Reduction in the cost to launch into the market.
- Promoting technological innovation.
- Simplifying international trade
- Improvising the ability to accept change and efficacy of national economies and remaining competitive. [11]

CONCLUSION:

In this era of advance research and development, technologies can have both advantages and disadvantages on the human beings. Therefore, a stringent and proper regulations and rules should be present in every step. To market a qualitative product pre-market procedure and post-market procedures are carried out. Pre-market notification process is followed for the medical devices by 90% of the manufacturer. Pre-market approval process is highly complicated than pre-market notification process. For High-risk medical devices clinical studies should be performed strictly. Moreover, the advance regulatory structure is lacking government active participation, GHTF guideline are to be aligned to improvise focus and sector to make on clinical trial studies.

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