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Comparative Study of Classification of Medical Devices in US, India, EU & Australia

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Abstract:
The classification of medical devices is fundamental to ensuring their safety and efficacy. However, these classifications vary between regions, impacting market access and patient safety. The primary aim is to compare and contrast the medical device classification systems in the US, EU, Australia & India to uncover both commonalities and differences, ultimately enhancing our understanding of global regulatory practices. The study conducts an in-depth analysis of regulatory documents and guidelines, identifying the key criteria, risk assessment factors, and classification processes used in each region. The study reveals that while the classification systems in the US, EU, Australia & India are all risk-based, they differ in the specifics of their criteria, risk assessment, and classification rules. The European Union's Common Technical Specification system stands out for its emphasis on clinical evaluation, while the USA's emphasis on intended use is notable. India focuses on the duration of use, and Australia considers both duration of use and invasiveness. The study emphasizes that although these systems have unique approaches, they share the common goal of safeguarding patient health and promoting innovation. Understanding these regional disparities and common principles is crucial for medical device manufacturers, regulatory bodies, and healthcare practitioners seeking to navigate the global market effectively. This study offers insights that can foster international harmonization efforts, enhance patient safety, and streamline market access for medical devices.
Key words: Medical Device, Guidelines, Safety & Efficacy.

Introduction: Background

The regulation of medical devices is a topic of paramount importance, as it directly impacts public health and the accessibility of cutting-edge healthcare technologies. Various countries have implemented distinct classification systems for medical devices, reflecting their unique healthcare landscapes, regulatory priorities, and public health concerns. In the past, numerous studies have investigated the medical device classification systems of individual countries, shedding light on the intricacies and variations in these regulations.

While past research has provided valuable insights into national regulatory frameworks, there is a growing need for a comprehensive comparative analysis of medical device classifications in multiple key regions, including the US, EU, Australia & India. Such a study is essential due to the globalization of the medical device market and the increasing international trade of these products. Understanding the differences and commonalities in classification systems is critical for manufacturers seeking to navigate the complex global regulatory landscape efficiently and ensure the safety and effectiveness of their products across diverse markets.

Importance and Purpose:

The proposed investigation aims to bridge this knowledge gap by offering a comprehensive comparative study of medical device classification systems in the US, EU, Australia & India. This research will explore the underlying principles, criteria and processes that inform the classification of medical devices in these regions. By examining the similarities and disparities, we seek to provide valuable insights for industry stakeholders,

regulatory authorities, and healthcare professionals, facilitating informed decision-making and harmonization efforts.

Hypothesis:

The study hypothesizes that while each region's classification system is influenced by its specific healthcare priorities and regulatory philosophies, there will be notable commonalities, as the ultimate goal in all regions is to ensure the safety and efficacy of medical devices. The investigation will uncover these shared elements while highlighting the unique features that define each region's approach to medical device classification.

Results And Discussion:

US Medical Device: A medical device is any appliance, instrument, substance, apparatus, or other item intended for human use and intended for any of the following uses:

- Monitoring, treatment, or relief of disease; diagnosis, prevention, therapy; or compensation for injury or handicap.
- Any mix of these applications is also included under this phrase.
- They can be used alone or in conjunction with other hardware and software to enable the device to function as intended.
- Analyzing, modifying, or swapping out a physiological or skeletal system.

Medical devices are an essential part of patient care because they regulate conception and do not complete their primary intended action in or on the human body, despite the fact that they may be made to function more easily by pharmacological, immunological, or metabolic routes. Dialysis machines and tongue depressors are two examples of high-tech medical devices. The problems are made worse by the fact that most medical equipment suffers power fluctuations. Thus, the crucial component of patient and healthcare provider safety is included together with gadget performance. Global norms and guidelines have been established to guarantee compliance with safety regulations and timely delivery of pertinent technologies. Because of increasing economies and more awareness, people are becoming more conscious about their health. Regardless of cost, people are willing to pick cutting-edge tools and approaches to improve their health. Medical devices have therefore witnessed a significant increase in the healthcare industry. The medical device industry also has various subsectors, such as imaging, surgery, orthopedics, cardiology, and diagnostics.

The Centre for Medical Devices and Radiological Health (CDRH) of the FDA regulates nearly 6,000 different types of medical devices, and the classification given to each type is listed in the Medical Device Product Classification database. Federal regulations (such as the Code of Federal Regulations, Title 21) specify conditions that must be met for CDRH to approve or clear devices sold in the United States, depending on the device classification and other circumstances.

Classification based on Risk (21 CFR 860):

Medical device risk classification was created by federal legislation (Federal Food, Drug, and Cosmetic Act, section 513). Medical device regulations are developed according to the relative risk of the equipment and are divided into classes. Regulatory classes I, II, and III are used to group devices according to the degree of control required to ensure a reasonable degree of safety and efficacy. (2)

Class I devices are governed by the fewest regulations, and Class III devices are governed by the most stringent regulations. As the device class moves from Class I to Class II to Class III, regulatory constraints increase.(2)
Each device class is under regulatory control:

Table No:1 Classification of Medical Devices:(3)

Sl No.	Class	Level of Risk	Examples
1	I	Low risk	Bandages, Tongue depressors.
2	II	Moderate risk	Powered wheelchairs, Infusion pumps.
3	III	High risk	Pacemakers, Implantable defibrillators.

Class I: Class I devices are relatively low risk level devices with minimum safety considerations for the user; general control means a general set of guidelines need for safety.

Examples are: prescription sunglasses or elastic bandages.

Quality systems, labelling, medical device reporting (MDR), adulteration/misbranding, electronic establishment, registration, electronic device listing, premarket notice [510(k)], and registration are a few instances of general controls.

Class II: Most of the devices are classified as Class II, or intermediate-risk, meaning that "special controls" are needed to guarantee the safety of the user. For FDA premarket examination and clearance, the majority of Class II devices need to go through the 510(k) premarket notification process. They might also be subject to tight regulations, much like Class III devices.

Examples are: pregnancy kits and motorized wheelchairs. There are currently over 800 Class II devices are in the market.

Class III: Class III devices are classified as high-risk devices and include implantable and life-supporting devices. Class III criteria apply to new technological devices that do not currently have a substantially equal alternative available on the market.

Examples are: pacemaker.

Types of Applications for Medical Devices

- IDE
- Premarket Notification 510 (K)
- Pre-Market Approval

1. 21CFR Part 812 -IDE (Investigational Device Exemption):

An experimental device may be used in a clinical study under an investigational device exemption (IDE) to collect the safety and efficacy data required to support an FDA Premarket Notification 510(k) submission or Premarket Approval (PMA) application. A clinical research project involving a device with a high level of risk requires permission from both the FDA and the Institutional Review Board (IRB) before it can begin. Just before the investigation begins, the IRB permission is necessary for experiments using equipment that isn't too dangerous.(4) The following conditions must be met before devices that do not yet have marketing approval can be clinically evaluated:

- An IRB - approved investigational plan. The FDA must additionally approve the IDE if the research includes a major risk device. Other requirements include:
- All patients' informed consent;
- Device labelling indicating that it is specifically made to be utilized in research;
- Research monitoring; and
- Required records and reports.

Approved research devices may legally be supplied under an IDE without further adherence to F D & C Act regulations that would apply to commercially dispersed devices. As long as the gadget is covered by warranty, sponsors are exempt from filing a pre-market approval or 510(k) pre market notification, registering their firm, or listing the product. 510(k) pre-market notification.

To market a Class I, II, or III device intended for human use in the United States, a pre-market notification 510(k) application must be filed with the FDA, unless the device is exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) 510(k) requirements and does not exceed the limitations of exemptions in Section.9 of the FD&C Act.[5]

PMA

Premarket Approval Application (PMA) approval is required for Class III devices under federal law.

Under federal law, devices that do not fall into a category that was marketed before to The Medical Device Amendments of 1976 (also known as pre-amendment devices) are automatically included in Class III. Additionally, devices are categorised by the FDA as class III devices if there is insufficient data to make a conclusion about their safety and effectiveness or if there is an unjustified risk of sickness or harm and neither special nor general controls can adequately assure the device's safety and effectiveness. These devices are designed to stop health issues in individuals or to help sustain or support human life.

Medical Devices Approval Procedure in US:

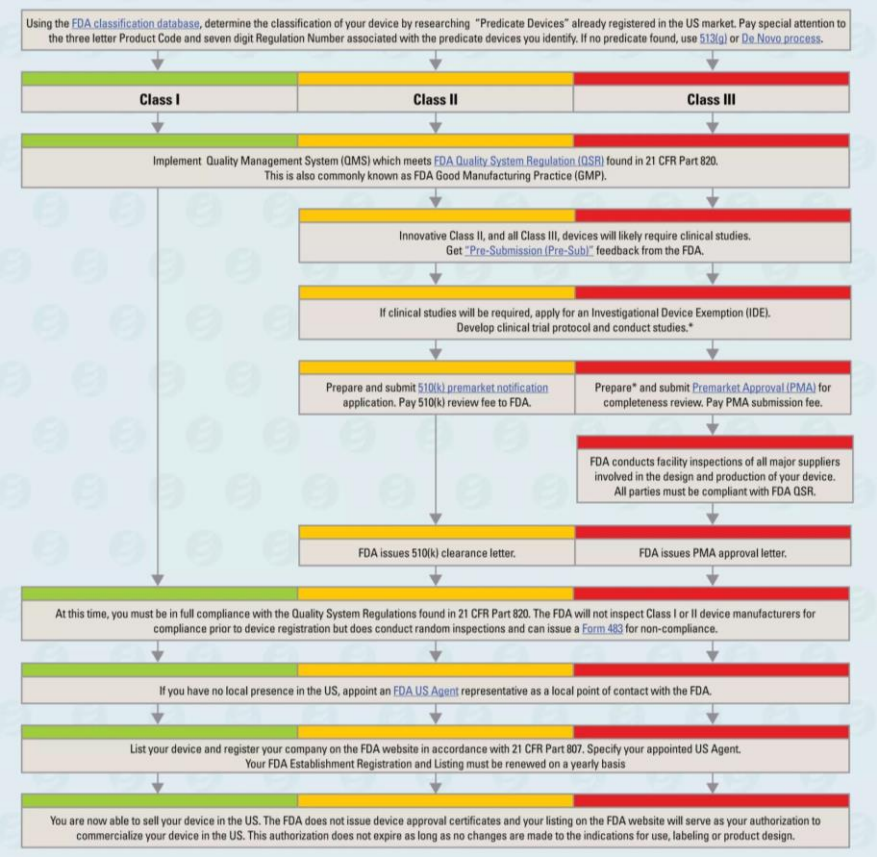

Figure 1: Medical Devices Approval Procedure in US

❖ **INDIA**

Definition:

- Any instrument, apparatus, software, substantial, or item that is used alone or in combination is considered a medical device. This comprises programming that the manufacturer intended to be used exclusively for symptomatic or potentially curative purposes and is necessary for the device's permitted use. The creator of the gadget believes that people will utilise it for illness detection, treatment, and prognosis in addition to examination, diagnosis, and easing.
- Supplies for in vitro analysis; protective dressings; gauzes; staples; stitches; ligatures; and an infinite variety of packs of blood components covered under sub-provision I
- Items including sanitizers, bug sprays, and mechanical contraceptives (condoms, IUDs, and tubal rings) that are recommended under sub-statement (ii),
- Devices periodically updated in accordance with sub-proviso (iv) of condition (b) of sec Currently, the Indian government is determined to separate medical devices from medications in order to promote R&D, production, and imports into the nation.

Classification:

The MDR 2017 Guidelines serve as the foundation for the Indian classification system, which is based on factors such as intended use, risk level, mode of distribution, the degree of invasion into human body. Currently, the Indian regulatory framework is in a state of transition, requiring import licences only for a limited range of product kinds. During this grace period, all additional medical devices may be submitted voluntarily. Non regulatory medical equipment of all class A and B will have 12 months (i.e., by October 1, 2022) to get an import licence following this voluntary period. Class C and D devices will have 24 months, or until October 1, 2023, to comply with the same standard. Generally, classification of Medical Devices based on the risks associated with them; the particular medical device classification is dictated by its intended use and purpose. The CDSCO

classification for medical devices covers a wider variety of devices, such as cannulas and stents, in more narrowly defined groupings.

Table No:2 Classification of Medical Devices in India:

Sl No.	Class	Risk Level	Examples
1	A	Low risk	Surgical Dressing Surgical gloves, Tongue depressors, and Non-invasive devices.
2	B	Low moderate risk	Catheters Nebulizers, Blood pressure monitors, and Thermometers.
3	C	Moderate high risk	Catheters, Bone fixation plates, and Surgical drapes.
4	D	High risk	Implantable devices, Heart valves, and Certain active devices.

Table No:3 List of Notified Medical Devices in India:

S. No	Name of the Device	Notification Number	Date of Notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HBsAg and HCV	GSR 601(E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone Cements	S.O. 1468 (E)	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005
15	Ablation Devices	S.O. 237(E)	25-01-2016

Table No:4 List of Newly Notified Medical Devices:

Sl No	Name of the Device	Effective from
1	X-Ray Machines	April 1, 2021
2	CT Scan Equipment	April 1, 2021
3	MRI Equipment	April 1, 2021
4	PET Equipment	April 1, 2021
5	Defibrillators	April 1, 2021
6	Dialysis Machines	April 1, 2021
7	Bone Marrow Cell Separators	April 1, 2021
8	All Implantable Medical Devices	April 1, 2021
9	Ultrasound Devices	November 1, 2021
10	Disinfectants and insecticides	-
11	Class A (Measuring or Sterile) and All Class B	October 1, 2022

Medical Devices Approval Procedure in India:

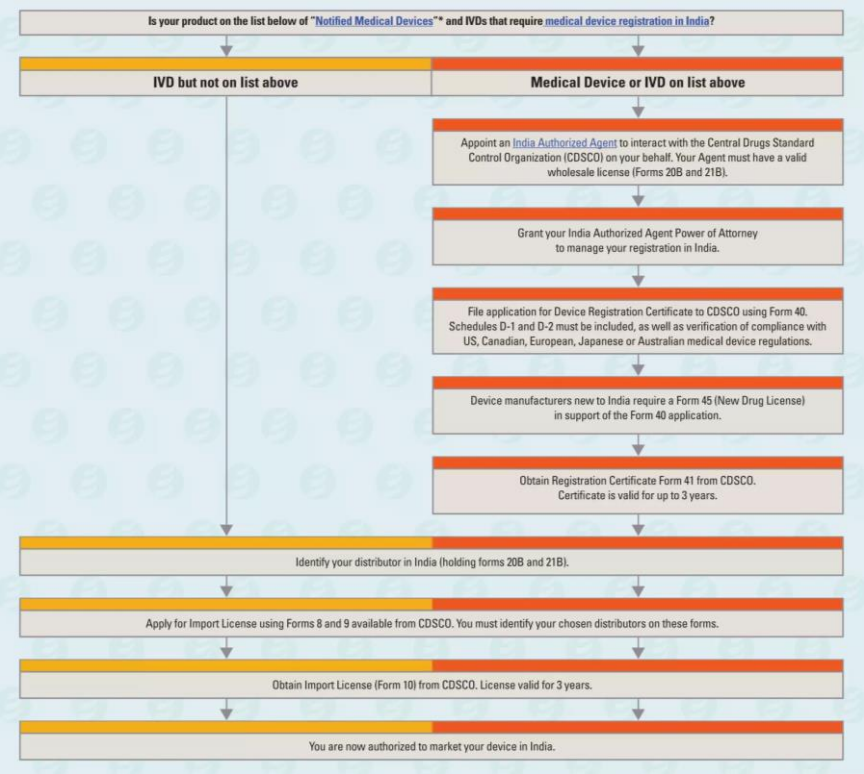

Figure 2: Medical Devices Approval Procedure in India

❖ **EUROPE**

Medical Device Medical devices are tools, equipment, software, etc. that are expected to be used singly or in combination for a therapeutic purpose. They must pass a congruity assessment in the European Union (EU) to demonstrate that they fulfil the legal requirements necessary to ensure their safety and smooth operation. The European Medicines Agency (EMA) is connected to the regulatory interaction, even if they are governed at the EU Part State level. Once a medical gadget has passed a congruity test, manufacturers can label it with the CE (Conformity European) mark.

A review of the manufacturer's quality framework and, depending on the type of device, an examination of specialised documentation from the producer regarding the functionality and safety of the item are typically included in the similarity evaluation.

U member states designate qualified entities to oversee similarity evaluations. Advise bodies will need the evaluation of specified expert panels for some high-risk gadgets before endorsing congruity. The expert and sensible assistance of EMA is beneficial to these master boards.

The told body ought to wait for a logical evaluation from EMA in a few different situations before providing a CE testament.

EMA clearly possesses regulatory authority over each class of medical device, specifically in relation to in vitro diagnostics. According to the following, they are:

- Prescription drugs used in combination with medical devices: EMA assesses the safety and efficacy of these combinations. This is crucial for the restorative item's concentrated system application.
- Medical devices with an auxiliary restorative substance: In three scenarios—if the auxiliary substance is derived from human blood or plasma, if it has recently been evaluated by the EMA, or if it falls within the required scope of the combined methodology—the regulatory body is advised to seek the EMA's logical assessment on the quality, security, and usefulness of the auxiliary restorative substance.
- Companion diagnostics, often known as "in vitro diagnostics" — if the last choice falls within the purview of the focused strategy, the recommended body should seek EMA's logical assessment on the suitability of the buddy demonstration to the restorative item.

- Medical equipment composed of substances that are essentially consumed — the body is advised to seek the rational evaluation of a power source that is equipped. The EMA expresses rational opinions regarding the content's compliance with the requirements outlined in Mandate 2001/83/EC Addition I.
- Medical device expert panels that provide hypotheses and viewpoints to advisory bodies about the rational assessment of particular high-risk MDs and IVDs are maintained by the EMA.

Definition:

According to the European Medicines Agency, a MD is an instrument, mechanical assembly, appliance, programming, embed, reagent, material, or other item that the sponcer expects to be used, alone or in combination, for humans for at least one of the following specific therapeutic reasons.

- Detection, prediction, observation, forecast, estimation, abatement or treatment of disease,
- Identifying, diagnosing, treating, relieving, or financing a physical problem or disability,
- Analysis, replacement, or alteration of the physiological or compulsive interaction or condition, or of the living systems,
- Providing information via In-Vitro evaluation of sample taken from the human body, such as organ, blood, and tissue donations; additionally, providing information about substances that, although not accomplished by pharmacological, immunological, or metabolic means in or on the human body, may nevertheless be enhanced by such means.

Additionally, the following products will be regarded as medical devices:

devices intended specifically for the cleaning, sanitization, or cleansing of the devices mentioned in Article 1(4) and in the main body of this point; - devices for the control or backup of origination.

Medical Device classification:

Based on their intended use and risks MDs will be categorized into classes I, II a, II b, and III.

Table No:5 New MDs classification:

S No	Class	Risk Level	Examples
1	Class I	**Low risk** • General safety standards • Manufacturers can declare compliance With the essential requirements. The Class I MDs are approved by regulatory authorities, and the manufactures themselves can issue the Comformite European mark (CE mark).	Bedpans, Sterile dressings, Gloves, Hospital Beds.
2	Class II a	**Medium risk** • General standards, quality systems, Special controls • Manufactures must submit a dossier containing all essential supporting documents, both clinical and non-clinical.	Surgical blades, Ultrasonic diagnostic equipment, Suction equipment, Powered wheelchairs, Hearing aids.
3	Class II b	**Medium to high risk** • Generally, standards, quality systems, Special controls • The maker must file a Manufacture's Declaration stating that the product conforms to the medical device regulations and other important requirements.	Infusion pumps, Ventilators, Some Implants, Surgical; Lasers, Radiotherapy equipment.
4	Class III	**High risk** • Although clinical trials are advised, the majority of them are nonrandomized and single-arm • Require pre-market review, including bench testing, clinical trials, and animal studies, providing proof of safety and effectiveness.	Many Implants: Replacement heart Valves, Breast implants Drug-eluting cardiac Stents, Peacemaker, Implantable defibrillators.

Medical Devices Approval Procedure in EU:

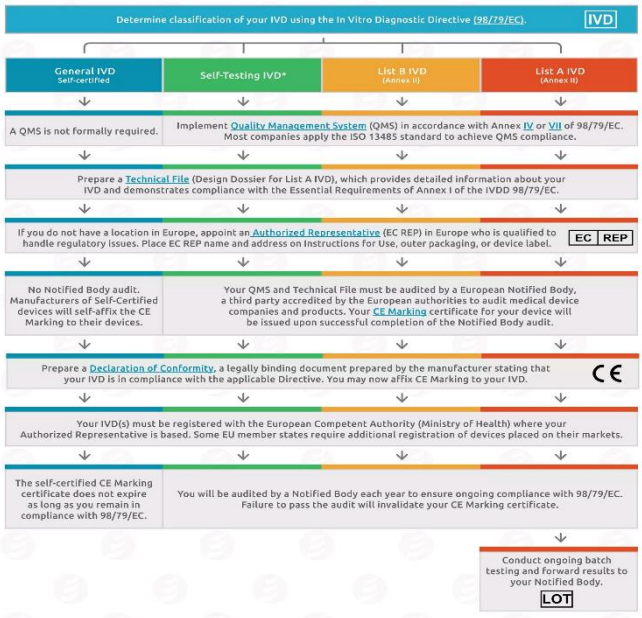

Figure 3: Medical Devices Approval Procedure in EU

AUSTRALIA

Medical Devices: Therapeutic Goods Act 1989 is the federal legislation that governs MDs in Australia. The TGA is responsible for implementing the Act. To guarantee quality, safety, and efficacy, the TGA controls the supply of medicinal products, including medications and medical devices. Medical practice is not regulated by the TGA. The three main methods used to control the supply of therapeutic goods are post-market surveillance, manufacturer licensing, and pre-market evaluation. The Department of Health and Ageing in Australia is home to the TGA division. Its main responsibility is to regulate therapeutic goods nationally, a term that encompasses pharmaceuticals, medical equipment, and associated commodities.

Pre-market clinical trials have not been conducted on medical devices in the same manner as pharmaceutical drugs. Furthermore, without being put through human trials, medical devices alter and adapt over time. Medical devices regulation is a dynamic and intricate field. A variety of reports and reform ideas pertaining to the Australian TGA have been presented in recent times.

According to TGA Medical Device is Defined as "Any Instrument, apparatus, appliance, material, or software intended to diagnose, prevent, monitor, treat, and alleviate disease". [(5)]

Medicines and MDs are regulated by the TGA, which is a division of Department of Health and Ageing of Australia.

1. Previously, there were little regulatory constraints to forbid the use of subpar gadgets and medical device laws were unusual in many nations.
2. As a result, it became necessary to create regulatory policies on medical devices in order to evaluate their efficacy, safety, and quality.
3. Thankfully, there has been a remarkable shift in the regulatory framework for MDs since the early 1980s.
4. Because different nations and regions now have distinct medical device regulations, there is a need to harmonize legislation to reduce regulatory barriers and speed up access to safety, efficacy and Quality of Medical Devices.
5. Keeping this backdrop in mind, a review of the different medical device rules from the world's main economies will precede a discussion of other relevant medical device legislation.

Definition:

A therapeutic product may be categorised as a medical device (medicine is not included in this definition) if it

satisfies these requirements and does not derive its principal intended effect from immunological, chemical, pharmacological, or metabolic processes.

- Prevent, identify, treat, or lessen an illness, condition, flaw, or injury
- Any device, material, instrument, appliance or other item (used separately or in combining with the software required for its proper application) that The individual whose name is being submitted desires for it to be used for human use in one or more of the ways listed below:
  1. The identification, management, monitoring, prevention, or relief of illness;
  2. The identification, tracking or payment of damage or handicap;
  3. examination, auxiliary, or alteration of a physiological process or the anatomy;
  4. conception control;
- And that, although it may be aided in its function, does not accomplish its primary intended action in or on the human body through pharmacological, immunological, or metabolic means; or Any device, equipment, appliance, substance, or other article listed under Therapeutic Goods Act 1989, subsection (2A);
- Any item that falls within one of the classes of items listed in Therapeutic Goods Act of 1989, subsection (2B), including instruments, apparatus, appliances, materials, and other objects;

Classification: According to Table 5 of the Australian Therapeutic Goods Regulation 2002, MDs are categorized in Australia. Medical devices are categorized according to the use for which they are designed. The classification guidelines specifically address the extent of invasion within the human body, the duration and location of usage, and the device's reliance on an energy source other than the body or gravity. Medical devices will be categorized into one of the primary groups based on the degree of risk involved.

Table No 5: Medical Device classification of Australia:

Research scholar, Department of Pharmaceutics, Regulatory Affairs group, JSS College of Pharmacy, Mysuru.

S No	Class	Risk Level	Examples
1	Class I	Low	Surgical retractors Tongue depressors
2	Class1- Supplied sterile Class1- With a measuring function Class2a	Low to Medium	Sterile surgical Gloves, Medicine up with specific unit measurement, Dental drills; Ultrasound machines; Digital or infrared thermometers
3	Class 2b	Medium to High	Surgical lasers Diagnostic x-ray
4	Class3	High	Prosthetic heart valves Absorbable surgical sutures Hip prostheses Pacemakers

Medical Devices Approval Procedure in Australia:

Research scholar, Department of Pharmaceutics, Regulatory Affairs group, JSS College of Pharmacy, Mysuru.

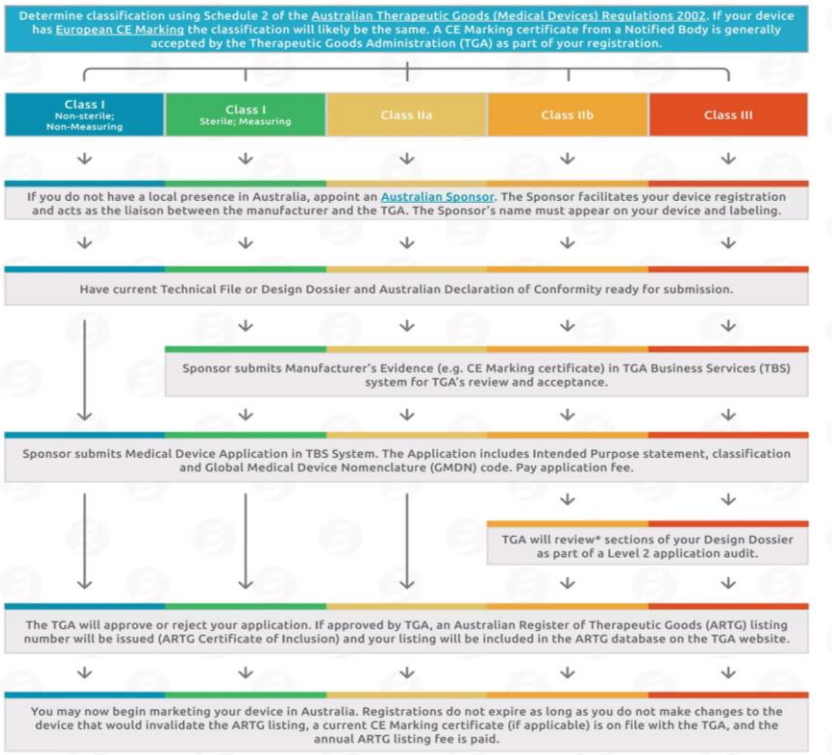

Figure 4: Medical Devices Approval Procedure in Australia

Conclusion:

This study provides an information related to differences and similarities between the regulatory frameworks of the US, India, EU & Australia. In our comparative analysis of medical device classification. Our investigation has shown the following important conclusions:

Different Classification Standards: Different standards are used by different regions to classify medical devices. While India takes into account the length of usage, Australia assesses both the invasiveness and the duration of use, Europe places more emphasis on clinical evaluation, the US prioritises intended use.

Risk-Oriented Methods: A risk-based classification system is used in all four regions, placing a strong emphasis on patient safety. This emphasizes our common goal of guaranteeing the efficacy and safety of medical equipment. Complexity and Diversity: Each classification system reflects the unique healthcare environments and regulatory agendas of each country by being complex and diverse.

These findings are valuable because they have the potential to improve patient safety, aid in international trade, and guide attempts to harmonize regulations. Effective product development and market entrance strategies can be facilitated by medical device manufacturers having a better grasp of the unique requirements in these locations. Through the identification of areas of convergence and divergence, regulatory organizations can provide a more streamlined and globally uniform approach by potentially aligning their regulations.

In the end, this study recognizes the need for region-specific concerns while simultaneously acting as a first step towards creating a more unified and harmonized worldwide regulatory environment for medical devices. It reaffirms that, in spite of divergent methodologies, the primary objective of these classifications is to safeguard patient well-being and foster creativity, highlighting the mutual dedication to guaranteeing the security and effectiveness of medical devices worldwide.

Comparative Studies

S.No.	Criteria	US	INDIA	EU	AUSTRALIA
	Regulatory Agency	U.S. Food and Drug Administration (USFDA)	Central Drug Standards Control Organization (CDSCO)	European Medicines Agency (EMA)	Therapeutic Goods Administration (TGA)
	Pharmaceutical Product	Medical Devices	Medical devices	Medical devices	Medical devices
	Type of application	Marketing Authorization Application	Marketing Authorization Application	Marketing Authorization Application	Marketing Authorization Application
	Guidelines/ Regulations	21 CFR part 814.42- Medical Devices	Schedule M, Schedule M III-GMP Schedule Y-Clinical Trials	Directive 93/42/EEC-Medical Device Directive 93/79/EC- CE Marking	Australian Regulatory Guideline for Medical Devices (ARGMD)
	Application Submission	Electronic Submission	Electronic Submission	eSubmission Gateway / Web Client	Online Submission

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