



COMPARATIVE ANALYSIS OF MEDICAL DEVICE REGULATION ACROSS KEY MARKETS, IN INDIA, THE US, AND THE EU

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ABSTRACT

Key markets have very different medical device regulations, which affect product clearance, commercialisation, and post-market surveillance. In order to guarantee patient safety and product effectiveness in international markets, medical device regulation is essential. The regulatory systems for medical devices in three important markets, the US, India, and the EU, are examined in this comparative study. The Medical Device Regulation (MDR) and the In-vitro Diagnostic Regulation (IVDR) oversee the EU's strict regulatory procedure, which places a strong emphasis on clinical performance and product safety. With an emphasis on evidence-based evaluation, the Food and Drug Administration (FDA) in the US requires pre-market approval or clearance through processes like 510(k) and Premarket Approval (PMA). Concentrating on evidence-based reviews. With a focus on quality control and post-market surveillance, India's regulatory framework, which is overseen by the Central Drugs Standard Control Organization (CDSCO), is changing to conform to international standards. In order to handle new issues in the medical device industry, India is currently fortifying its regulatory framework, whereas the US and the EU have robust, well-established systems. The parallels, differences, and possible effects of these restrictions on industry stakeholders are examined in this article, along with the opportunities and difficulties associated with entering international markets. In order to guarantee compliance and market access, the findings are intended to assist manufacturers and regulatory experts in navigating the intricate regulatory environments. Key markets have very different medical device regulations, which affect product clearance, commercialisation, and post-market surveillance. In order to guarantee patient safety and product effectiveness in international markets, medical device regulation is essential. The regulatory systems for medical devices in three important markets, the US, India, and the EU, are examined in this comparative study. The Medical Device Regulation (MDR) and the In-vitro Diagnostic Regulation (IVDR) oversee the EU's strict regulatory procedure, which places a strong emphasis on clinical performance and product safety. With an emphasis on evidence-based evaluation, the Food and Drug Administration (FDA) in the US requires pre-market approval or clearance through processes like 510(k) and Premarket Approval (PMA). Concentrating on evidence-based reviews. With a focus on quality control and post-market surveillance, India's regulatory framework, which is overseen by the Central Drugs Standard Control Organization (CDSCO), is changing to conform to international standards. In order to handle new issues in the medical device industry, India is currently fortifying its regulatory framework, whereas the US and the EU have robust, well-established systems. The parallels, differences, and possible effects of these restrictions on industry stakeholders are examined in this article, along with the opportunities and difficulties associated with entering international markets. In order to guarantee compliance and market access, the findings are intended to assist manufacturers and regulatory experts in navigating the intricate regulatory environments.

KEYWORDS: comparative analysis, classification, Premarket Approval, medical device regulation, premarket notification 510(k), premarket scrutiny, surveillance.

INTRODUCTION

Medical device regulation ensures that medical products are safe, effective, and manufactured to meet stringent quality standards. As healthcare systems evolve globally, various regions adopt unique regulatory frameworks for

medical devices. This comparative analysis focuses on the regulatory environments in three key markets: India, the United States (US), and the European Union (EU).^[1] Each region's regulatory approach is designed to address public health concerns, ensuring that medical devices are

both safe and effective. However, these regulations differ in their processes, timelines, and requirements. By examining the regulatory systems of these regions, stakeholders can gain a better understanding of global medical device standards and their implications for market entry.^[2]

Regulatory Authorities and Framework

1. India

- Regulatory Authority: Central Drugs Standard Control Organization (CDSCO)
- Key Framework: The regulation of medical devices in India is governed by the Medical Devices Rules (MDR), 2017, under the Drugs and Cosmetics Act.
- Example: Implantable Cardiac Devices like pacemakers are subject to CDSCO's rigorous review for higher-risk devices (Class D).^[3]



Fig. 1: logo of CDSCO.

2. United States (US)

- Regulatory Authority: Food and Drug Administration (FDA).
- Key Framework: The FDA regulates medical devices under the Federal Food, Drug, and Cosmetic Act, with guidance from the Center for Devices and Radiological Health (CDRH).
- Example: Pacemakers in the US are regulated under Class III, requiring Premarket Approval (PMA) based on substantial clinical evidence.^[5]



Fig. 2: Logo of the FDA.

3. European Union (EU)

- Regulatory Authority: European Medicines Agency (EMA), along with national regulatory bodies and Notified Bodies for device certification.
- Key Framework: Medical devices in the EU are governed by the Medical Device Regulation (MDR) 2017/745 and In-vitro Diagnostic Regulation (IVDR) 2017/746.
- Example: Implantable Devices like pacemakers must obtain a CE mark through a Notified Body to enter the EU market.^[4]



Fig. 3: Logo of European Medicines Agency.

CLASSIFICATION

1. INDIA

India follows a risk-based classification system under the Medical Devices Rules (MDR), 2017. Medical devices are categorized into four classes:

- Class A: Low-risk devices (e.g., surgical gloves, tongue depressors)
- Class B: Low-to-moderate risk devices (e.g., dental materials, thermometers)
- Class C: High-risk devices (e.g., infusion pumps, ventilators)
- Class D: Very high-risk devices (e.g., pacemakers, heart valves, implantable devices)

• Key Points

- Lower-risk devices (Class A and B) generally require less stringent regulatory oversight and can often be self-certified by manufacturers.
- Higher-risk devices (Class C and D) require more rigorous testing, clinical data, and approval processes.^[6]

2. UNITED STATES (US)

The FDA uses a three-class system based on risk, where each class corresponds to the regulatory requirements for approval.

- Class I: Low-risk devices (e.g., bandages, manual wheelchairs). These are generally subject to General Controls and may be exempt from premarket notification (510(k)).
- Class II: Moderate-risk devices (e.g., infusion pumps, diagnostic ultrasound). These require General Controls and Special Controls, and manufacturers must typically submit a 510(k) Premarket Notification demonstrating that the device is substantially equivalent to a legally marketed device.

- Class III: High-risk devices (e.g., pacemakers, heart valves, deep brain stimulators). These require General Controls, Special Controls, and the most stringent oversight, including Premarket Approval (PMA), which involves clinical trials and substantial evidence of safety and efficacy.

• Key Points

- The FDA's classification is rooted in the level of risk posed by the device, with Class III devices requiring the most robust clinical evidence.
- Some Class I devices are exempt from premarket notification, while Class II and III devices almost always require premarket submission.^[8]

3. EUROPEAN UNION (EU)

The EU follows a risk-based classification system as defined in the Medical Device Regulation (MDR) 2017/745 and In-vitro Diagnostic Regulation (IVDR) 2017/746.

- Class I: Low-risk devices (e.g., non-invasive devices like tongue depressors, dental fillings). These devices may be self-certified by the manufacturer, but they must still meet all regulatory requirements.
- Class IIa: Medium-risk devices (e.g., blood pressure monitors, hearing aids). These devices must undergo assessment by a Notified Body (an independent organization designated by the government).
- Class IIb: Higher-risk devices (e.g., infusion pumps, anesthesia equipment). These require more detailed assessment by a Notified Body.
- Class III: High-risk devices (e.g., pacemakers, prosthetics). These require extensive evaluation, including clinical trials, and an in-depth review by a Notified Body.

• Key Points

- The classification system in the EU is aligned with the risk of the device, with Class III devices subjected to the most stringent regulations.
- The introduction of the MDR 2017 brought more stringent requirements, particularly in clinical evidence, post-market surveillance, and traceability.^[7]

PREMARKET APPROVAL

1. India: CDSCO Premarket Approval Process

Step 1: Device Classification

- Devices are categorized as Class A, B, C, or D depending on risk, with Class A being the lowest and Class D the highest.
- Classification is based on intended use, duration of use, invasiveness, and local/systemic effects.

Step 2: Registration Application

- Application for device registration or manufacturing/import license is submitted through Form MD-14 (import) or Form MD-4 (manufacturing).
- Required for Class B, C, and D; Class A (non-sterile, non-measuring) devices may only need self-certification.

Step 3: Submission of Technical Documentation

- Includes device description, risk analysis, manufacturing information, clinical data (if required), and labeling.
- A Plant Master File (PMF) and Device Master File (DMF) are also required.

Step 4: Clinical Investigation (If Required)

- For new or high-risk (Class C/D) devices, clinical data may be required.
- Clinical investigation approval must be obtained using Form MD-22, with ethics committee clearance.

Step 5: Notified Body Review & CDSCO Approval

- Notified Bodies inspect and assess the conformity of devices (mainly for Class B and above).
- Final approval/license is granted by CDSCO, followed by issuance of the MD-16 (import) or MD-6 (manufacture) certificate.^[9]

2. United States: FDA Premarket Approval Process

Step 1: Device Classification

- Devices are classified as Class I (low risk), Class II (moderate risk), and Class III (high risk).
- Classification depends on intended use and level of control needed.

Step 2: Identify Approval Pathway

Based on classification:

- Class I: Often exempt from premarket submission.
- Class II: Requires 510(k) clearance.
- Class III: Requires Premarket Approval (PMA).
- De Novo: For novel low/moderate risk devices with no predicate.

Step 3: Clinical Trials (if required)

- For high-risk devices or those without sufficient prior data, clinical trials must be conducted under an Investigational New Drug (IDE).

Step 4: Submission of 510(k) or PMA

- 510(k): Submit evidence of substantial equivalence to a predicate device.
- PMA: Submit complete scientific evidence, manufacturing data, clinical performance data, and labeling.

Step 5: FDA Review and Decision

- 510(k): Reviewed within ~90 days.
- PMA: Undergoes a rigorous review including advisory panel input (if needed), typically taking 180–320+ days.
- Result: FDA issues either an Approval Order or a Not Approvable Letter.^[11]

3. European Union: MDR Conformity Assessment Process

Step 1: Device Classification

- Classification into Class I, IIa, IIb, or III under MDR 2017/745, based on invasiveness, duration of use, and body contact.
- Manufacturers use MDR Annex VIII rules to determine classification.

Step 2: Identify Conformity Route

- Class I (non-sterile, non-measuring): Self-declaration of conformity.
- Class IIa/IIb/III: Requires a Notified Body for conformity assessment and CE certification.

Step 3: Clinical Evaluation and Technical File Preparation

- Prepare Technical Documentation, including:
- General Safety and Performance Requirements (GSPR)
- Risk Management Reports
- Clinical Evaluation Report (CER)
- Post-Market Surveillance (PMS) plan
- UDI and Labeling strategy

Step 4: Notified Body Review :

- Notified Body conducts an audit of the Quality Management System (QMS) and reviews the technical file.
- For Class III and some Class IIb devices, a Design Dossier review is mandatory.

Step 5: CE Certification

- Once the review is successful, the Notified Body issues a CE Certificate.
- The manufacturer can then affix the CE mark and begin distribution in EU member states.^[10]

Premarket Approval Process of Medical Devices

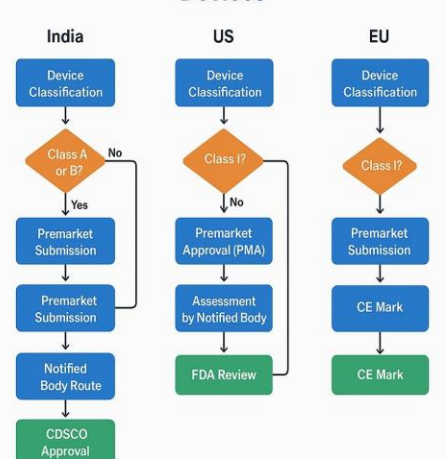


Fig. 4: Premarket approval process of medical devices.

PREMARKET NOTIFICATION 510(K)

1. India

- No 510(k) equivalent: India has its regulatory framework, governed by the Medical Device Rules, 2017.
- Regulatory Body : Central Drugs Standard Control Organization (CDSCO).

Requirements

- Device Registration: Medical devices must be registered with CDSCO.
- Licensing: Manufacturers need to obtain a license to market their devices.^[12]

2. United States (US)

- 510(k) Premarket Notification: Required for most devices, demonstrating substantial equivalence to a predicate device.
- Submission : Manufacturers submit a 510(k) application to the FDA.
- Review: The FDA reviews the application to determine substantial equivalence.

Requirements

- Device Description: Detailed description of the device
- Predicate Device: Identification of a predicate device
- Performance Data : Performance data to demonstrate substantial equivalence
- Labeling: Labeling that meets FDA requirements.^[13]

3. European Union

- No 510(k) equivalent: The EU has a different regulatory framework, governed by the Medical Device Regulation (MDR).
- Regulatory Body: National competent authorities and the European Commission play key roles.

Requirements

- CE Marking: Required for most devices, demonstrating compliance with EU regulations.
- MM6 - Conformity Assessment : Manufacturers must undergo a conformity assessment procedure.
- Technical Documentation: Manufacturers must maintain technical documentation.^[12]

Region	Notification Model	Key Feature	Governing Authority
US	510(k) Premarket Notification	Substantial equivalence to predicate	FDA (CDRH)
India	License via MD-5/MD-6	Risk-based registration	CDSCO
EU	CE Mark via Conformity Assessment	Safety and performance compliance	Notified Bodies under EU MDR

Fig. 5: Premarket Notification 510(k).

PRE- MARKET SURVEILLANCE AND REPORTING

Aspect	India	United States (US)	European Union (EU)
Regulatory Authority	CDSCO	FDA (CDRH)	Notified Bodies + Competent
Premarket Surveillance Definition	Risk; based review + technical dossier review	Part of 510(k) and PMA reviews (device tracking quality)	Covered under Clinical Evaluation and Risk
Preclinical Evaluation	Mandatory for all except exempt Class A devices	Mandatory for all except exempt Class A	Required under MDR Annex I and II
Clinical Evaluation Requirement	For Class C & D: clinical investigation may be required	Required for PMA, rarely for 510(k)	Mandatory for all classes, depth varies by class
Clinical Trials Regulation	Governed by GCP and ICMR; registered with	IND/IDE regulations; GCP required	GCP compliance; Clinical Investigation
Human Factor Engineering / Usability	Recommended for high, risk or complex devices	Required as part of design controls (21 CFR 820.30)	Mandatory under MDR for usability validation
Labeling Requirements	Conformity with MDR 2017, including UDI (phased)	Must meet FDA labeling and UDI requirements	Must comply with MDR Annex U UDI mandatory
Risk Management File	Required for Class B to D	Required under design controls (ISO 14971 accepted)	Mandatory for all devices under ISO 14971
Quality System Documentation	ISO 13486 mandatory for Class C & D	Quality System Regulation (21 CFR Part 820)	ISO 13485 compliance required across
Technical Documentation	Device Master File (DMF) + Performance	Device Master Record + Design	Technical Documentation per

Fig. 6: Pre-market surveillance and reporting.^{[2] [13]}

PREMARKET SCRUTINY

1. India

India has been evolving its regulatory landscape for medical devices, with significant strides made through the Medical Device Rules, 2017. While lower-risk devices may not require rigorous premarket scrutiny,

Class C and Class D devices are subject to more comprehensive evaluation, although the system still lacks the depth and sophistication seen in the US and EU.^[15]

2. US

The US follows a highly structured approach to premarket scrutiny, utilizing the 510(k) process for moderate-risk devices (Class II), which focuses on demonstrating substantial equivalence to an existing device, allowing for quicker market access. For high-risk devices (Class III), the Premarket Approval (PMA) process is more detailed and rigorous, including clinical trials and extensive data analysis. This system is highly efficient for device manufacturers, but it can also be time-consuming for high-risk devices.^{[16] [15]}

3. EU

The EU operates under a more centralized framework through Notified Bodies that review devices before they can be marketed. The Medical Device Regulation (MDR 2017/745) and In-Vitro Diagnostic Regulation (IVDR 2017/746) require that Class II and Class III devices undergo more comprehensive assessments, which often involve clinical evaluations and technical documentation. Compared to India, the EU has a more standardized and structured approach, particularly for higher-risk devices.^{[14] [15]}

Premarket Scrutiny for Medical Devices			
	India	US	EU
Regulatory Authority	CDSCO	Frouid Bundes	Notified Bodies
Device Classification	Class A (Low Ris)) to Class D (high Risk)	Class I (Low) 1- Class III (High)	Notified Bodies
Class I Devices	Self-certification (Class A)	510(k) evemption a general controls	Self-declaration (Class I nonseh-elle, non-measuring)
Class II Devices	Application with technical file, clinical data (B. C)	510(k) clearance (substantial equivalence)	Notified Body involvement lia and lib
Class III /High-Risk Devices	Clinical . Investigation + CDSCD avaluation (Class D)	Premarker Approval (PMA) with clinical data	Notified Body conformly assesment + clinical evaluation
Submission Requirements	Device Master File, Quality Certification, ISO 13465	Design Nstory file, Device Master Record, clinical data	Mandatory Clinical Evaluation for all especial y Class III
Assessment Body	CDSCO directly or through state Licensing Authorities	FDA	Notified Body (Class IIa and above)
Review Timeline	45 -150 days depending on device class	90 days (510(k), 180 - days (PMA)	6-18 months depending on clarification and Notified Body
Certification Outcome	License for manufacture/import	FDA Clearance (510(k) Approval (PMA) or De	CE Marking after Notified Body assesment

Fig. 7: Premarket Scrutiny for Medical Devices.^{[14] [15] [16]}

CHALLENGES AND OPPORTUNITIES

Fig. 8: Challenges and Opportunities in India, the US, and the EU.^{[17] [18] [19]}

COUNTRIES	CHALLENGES	OPPORTUNITIES
India	Regulatory gaps, limited post-market surveillance infrastructure, and delays in approvals.	Growing market, increasing government focus on healthcare.
United States (US)	Stringent approval processes, long time for market entry (especially for Class III).	Largest market for medical devices, well-established regulatory pathways.
European Union (EU)	Complex regulatory framework, challenges in transitioning MDR/IVDR.	Access to a large and diverse market, harmonized regulations across member states.

CONCLUSION

The comparative analysis of medical device regulations in India, the United States, and the European Union highlights the diversity and complexity of global regulatory landscapes. Each region adopts a distinct risk-based classification system and premarket approval

process, tailored to ensure device safety and effectiveness. The US and EU have well-established, structured regulatory pathways emphasizing clinical evaluation, technical documentation, and post-market surveillance. India, while evolving, is actively aligning its framework with global standards to enhance

regulatory rigor and market confidence. Manufacturers aiming for global market access must navigate these differing requirements strategically, balancing compliance with time-to-market considerations. Harmonization efforts and international collaborations can bridge regulatory gaps and create opportunities for innovation and patient access to safe, effective medical technologies. Ultimately, understanding and adapting to these regulatory nuances is essential for industry stakeholders to thrive in an increasingly globalized healthcare ecosystem.

REFERENCES

1. Gollaher, D., & Goodall, P. (2011). The globalization of health care: Can medical devices be regulated effectively? The Hoover Institution.
2. World Health Organization. (2003). Medical device regulations: Global overview and guiding principles. WHO Press.
3. Central Drugs Standard Control Organization (CDSCO). (2017). Medical Devices Rules, 2017. Ministry of Health and Family Welfare, Government of India.
4. European Commission. (2020). Medical Device Regulation (EU) 2017/745.
5. U.S. Food and Drug Administration (FDA). (2021). Overview of device regulation.
6. CDSCO. (2017). Classification of medical devices under Medical Devices Rules, 2017.
7. European Commission. (2021). Guidance on classification of medical devices under Regulation (EU) 2017/745.
8. U.S. FDA. (2023). Classify your medical device.
9. CDSCO. (2020). Guidance document for premarket approval of medical devices.
10. European Commission. (2021). Conformity assessment and CE marking under MDR.
11. U.S. FDA. (2022). Premarket approval (PMA).
12. Rathi, V. K., et al. (2015). The 510(k) pathway: Balancing innovation and patient safety. *JAMA*, 314(17): 1795–1796.
13. U.S. FDA. (2021). 510(k) premarket notification.
14. European Commission. (2020). Notified Bodies and conformity assessment under MDR.
15. Global Harmonization Task Force (GHTF). (2012). Essential principles of safety and performance of medical devices.
16. U.S. FDA. (2021). Device advice: Comprehensive regulatory assistance.
17. Bhargava, H., & Sharma, P. (2020). Medical device industry in India: Regulatory challenges and the way forward. *Indian Journal of Public Health Research & Development*, 11(3): 543–547.
18. Deloitte. (2018). Medical device regulatory challenges and global trends.
19. MedTech Europe. (2021). The European medical technology.