RESEARCH PAPER

Proposing a Unified Classification System for AI-Based Medical Devices

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Abstract

Background: The rapid integration of AI and Machine Learning (ML) into healthcare has created an urgent need for harmonized regulatory frameworks. Significant fragmentation persists across the United States (FDA), European Union (MDR), Japan (PMDA), Canada (Health Canada), United Kingdom (MHRA), Australia (TGA) and India (CDSCO), each maintaining distinct classification frameworks with varying risk stratification criteria. This fragmentation increases development costs, delays patient access, and creates competitive disadvantages for global manufacturers.

Objective: To conduct a comparative analysis of AI medical device regulatory frameworks across seven major regulatory bodies, identify convergence opportunities, and propose a unified risk classification system that harmonizes disparate approaches while accommodating jurisdiction-specific requirements.

Methods: A comparative legal and regulatory analysis was conducted through systematic review of primary regulatory documents and official publications from seven regulatory authorities. Four dimensions were examined: classification architecture, pre-market requirements, AI/ML-specific provisions, and post-market surveillance. The IMDRF SaMD risk categorization framework (N12) served as the foundational structure, integrated with practical requirements from each jurisdiction.

Results: While all regulatory bodies have adopted risk-based classification, significant variations exist in the number of risk classes (3–4), classification criteria, and pathway requirements. We proposed a unified four-tier system- Class I (Low Risk) through Class IV (Critical Risk) based on information significance (inform, drive, diagnose/treat) and healthcare situation severity. Key convergence areas include Predetermined Change Control Plans (PCCPs) and Good Machine Learning Practice (GMLP) standards.

Conclusion: The proposed framework provides a common language and decision matrix adaptable to local regulatory contexts while promoting international harmonization, reducing time-to-market, and supporting manufacturers, regulators, and healthcare stakeholders navigating the evolving AI medical device landscape.

Keywords: Artificial Intelligence, Machine Learning, Medical Device Regulation, Software as a Medical Device (SaMD), AI as a Medical Device (AIaMD), Risk Classification, IMDRF, FDA, MDR, Regulatory Harmonization, Healthcare Technology

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1. Introduction

1.1 Background

The integration of Artificial Intelligence (AI) and Machine Learning (ML) into medical devices represents one of the most transformative developments in modern healthcare. AI-based medical devices, encompassing Software as a Medical Device (SaMD) and AI as a Medical Device (AIaMD), are revolutionizing clinical practice across diverse domains including diagnostic imaging, clinical decision support, personalized treatment planning, and patient monitoring.(1,2) According to recent data from the U.S. Food and Drug Administration (FDA), over 1200 AI-enabled medical devices have received market authorization as of 2025, with the majority concentrated in radiology (77%), cardiovascular (10%), and neurology (5%) applications.(3,4)

The regulatory landscape for AI medical devices has evolved rapidly in response to these technological advances.(5) Unlike traditional medical devices with fixed functionality, AI/ML-based devices possess the unique characteristic of continuous learning and adaptation, enabling them to improve performance over time through exposure to new data.(2,6) This inherent adaptability presents both opportunities and challenges for regulatory frameworks originally designed for static hardware-based devices. The traditional pre-market approval paradigm, which assumes device characteristics remain constant throughout its lifecycle, requires fundamental rethinking to accommodate the dynamic nature of AI algorithms.(7,8)

1.2 The Challenge of Regulatory Fragmentation

Despite international efforts toward harmonization, significant regulatory fragmentation persists across major regulatory bodies. The United States employs a three-class risk-based system (Class I, II, III) under FDA oversight, while the European Union's Medical Device Regulation (MDR) utilizes a four-class system (Class I, IIa, IIb, III). Japan's Pharmaceuticals and Medical Devices Agency (PMDA), Canada's Health Canada, the UK's Medicines and Healthcare products Regulatory Agency (MHRA), Australia's Therapeutic

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Goods Administration (TGA) and India's Central Drugs Standard Control Organisation (CDSCO) each maintain distinct classification frameworks with varying risk stratification criteria and regulatory requirements.(9,10)

This regulatory fragmentation creates substantial challenges for medical device manufacturers seeking global market access. A device classified as low risk by one regulatory authority may face higher classification and more stringent requirements in another. This necessitates multiple regulatory submissions, duplicative clinical studies and extended time-to-market. These inefficiencies increase development costs, delay patient access to innovative technologies, and create competitive disadvantages for smaller manufacturers with limited regulatory resources.

The economic impact of regulatory fragmentation is significant. Industry estimates suggest that navigating multiple regulatory systems can increase time-to-market by 12-24 months and add millions of dollars in compliance costs.(11) These barriers disproportionately affect smaller companies and startups that may lack the resources to pursue multiple parallel regulatory pathways. The result is reduced competition, slower innovation, and delayed access to potentially beneficial technologies for patients and healthcare systems.(12)

1.3 Research Objectives

This research aims to address the challenge of regulatory fragmentation through the following objectives:

- To conduct a comprehensive comparative analysis of AI medical device regulatory frameworks across seven major regulatory authorities: USA, EU, Japan, Canada, UK, Australia and India.
- To identify commonalities, differences, and convergence opportunities in existing classification systems and regulatory requirements.
- To propose a unified risk classification system that harmonizes disparate regulatory approaches while accommodating jurisdiction-specific requirements.
- To provide actionable recommendations for regulatory authorities, manufacturers and healthcare stakeholders seeking to navigate the global AI medical device landscape.

1.4 Significance of the Study

The significance of this research extends across multiple stakeholder groups in the healthcare ecosystem. For regulatory authorities, the proposed unified framework offers a template for international harmonization efforts, potentially reducing the burden of bilateral and multilateral regulatory cooperation while maintaining appropriate safety standards. The framework provides a common reference point that can facilitate mutual recognition agreements and streamline the exchange of regulatory information across regulatory authorities.

For medical device manufacturers, particularly small and medium enterprises with limited regulatory resources, a harmonized classification system promises reduced regulatory complexity, lower compliance costs, and accelerated global market access. The current fragmentation forces manufacturers to navigate multiple classification systems, prepare different submission packages for each regulatory authority and potentially conduct redundant clinical studies to meet varying evidence requirements. A unified framework would enable manufacturers to develop standardized regulatory strategies, reducing time to market and enabling more efficient allocation of development resources.

For healthcare providers and patients, regulatory harmonization facilitates earlier access to innovative AI technologies that can improve diagnostic accuracy, treatment outcomes, and healthcare efficiency. When regulatory barriers delay market access, patients in some jurisdictions may be denied timely access to potentially life-saving technologies that are already available elsewhere. Harmonized frameworks can help ensure more equitable global access to medical innovation while maintaining the safety standards necessary for patient protection.

2. Methodology

2.1 Research Design

This study employs a comparative legal and regulatory analysis methodology, combining systematic document review with qualitative synthesis of regulatory frameworks. The research design encompasses three primary phases: (1) comprehensive documentation of existing regulatory frameworks across seven targeted regulatory bodies; (2) systematic comparison of classification systems, pre-market requirements, and post-market surveillance mechanisms; and (3) synthesis of findings into a proposed unified classification framework.

The comparative approach was selected to identify both convergent practices that can form the basis for harmonization and divergent approaches that may require reconciliation. By examining multiple regulatory bodies simultaneously, the study can distinguish between fundamental regulatory principles and jurisdiction-specific implementation details. This distinction is essential for developing a unified framework that respects legitimate differences in healthcare systems and regulatory philosophies while promoting convergence on core safety and effectiveness standards.

2.2 Data Collection

Data collection focuses on primary regulatory documents, guidance materials and official publications from each nation’s regulatory authority. Key sources included FDA guidance documents and 21 CFR regulations for the United States; Medical Device Regulation (EU) 2017/745 and MDCG guidance documents for the European Union; PMDA

notifications and ministerial ordinances for Japan; Health Canada guidance documents and Medical Devices Regulations for Canada; MHRA guidance and UK Medical Devices Regulations 2002 for the United Kingdom; TGA guidance and Therapeutic Goods (Medical Devices) Regulations for Australia; and CDSCO Medical Devices Rules, 2017 and draft guidance documents for India.

Secondary sources including peer-reviewed publications, industry reports, and regulatory news sources were consulted to supplement primary document analysis and provide context on implementation experiences. Data collection emphasized documents published between 2020 and 2025 to capture the most current regulatory approaches, though foundational documents with ongoing relevance were also included. The rapid evolution of AI medical device regulation required careful attention to publication dates and subsequent amendments or updates to guidance documents.

The data collection process was structured to ensure comprehensive coverage of each nation's regulatory framework, including classification criteria, pre-market submission requirements, quality management system expectations, clinical evidence standards, post-market surveillance obligations and AI-specific provisions. This comprehensive approach enables meaningful comparison across regulatory standards and identification of best practices that can inform the proposed unified framework.

2.3 Analytical Framework

The analytical framework for comparing regulatory systems was structured around four dimensions: (1) Classification Architecture- examining the number of risk classes, classification criteria and decision logic; (2) Pre-Market Requirements- analyzing quality management systems, clinical evidence requirements, and submission pathways; (3) AI/ML Specific Provisions- evaluating requirements for algorithm validation, change control, and continuous learning; and (4) Post-Market Surveillance- comparing vigilance reporting, periodic safety updates, and performance monitoring requirements.

2.4 Framework Development

The proposed unified classification system was developed through iterative synthesis of best practices identified across regulatory authorities. The International Medical Device Regulators Forum (IMDRF) SaMD risk categorization framework (N12) served as the foundational structure, providing the two-dimensional risk matrix based on healthcare situation and information significance. This framework was then integrated with practical regulatory requirements from each regulatory body to create a unified system that maintains theoretical coherence while ensuring practical applicability.

3. Results and Discussion

3.1 Overview of Regulatory Frameworks

The regulatory frameworks for AI-based medical devices across the seven regulatory bodies share fundamental similarities while exhibiting important differences in implementation. All regulatory bodies have adopted risk-based classification systems that stratify devices according to potential patient harm, with higher-risk devices subject to more stringent regulatory requirements. However, the number of risk classes varies from three (USA) to four (EU, Japan, Canada, UK, Australia, India), creating the first layer of regulatory complexity.

Table 1: Comparison of Risk Classification Systems Across Regulatory bodies

Jurisdiction	Classes	Low Risk	Moderate Risk	High Risk
USA (FDA)	3	Class I (Exempt)	Class II (510k)	Class III (PMA)
EU (MDR)	4	Class I	Class IIa/IIb	Class III
Japan (PMDA)	4	Class I	Class II	Class III/IV
Canada (HC)	4	Class I	Class II	Class III/IV
UK (MHRA)	4	Class I	Class IIa/IIb	Class III
Australia (TGA)	4	Class I	Class IIa/IIb	Class III
India (CDSCO)	4	Class A	Class B	Class C/D

3.2 United States (FDA) Framework

The U.S. Food and Drug Administration regulate AI/ML-based medical devices under the existing medical device framework established by the Federal Food, Drug, and Cosmetic Act. Devices are classified into Class I, II, or III according to a risk-based regulatory approach. In 2024, the FDA authorized 168 ML-enabled medical devices, with 94.6% cleared through the 510(k) pathway and 5.4% through the De Novo pathway.(13) All devices approved during this period were classified as Class II, reflecting the predominance of moderate-risk software-based AI applications. Recent regulatory developments, including Predetermined Change Control Plans (PCCPs) and lifecycle management guidance for AI-enabled devices, further strengthen the FDA's oversight of adaptive algorithms and post-market modifications.(14)

The FDA has developed specific guidance for AI/ML-based devices, including the "Predetermined Change Control Plan" (PCCP) framework that allows manufacturers to pre-specify planned modifications to AI algorithms without requiring additional submissions for each change.(15) This approach addresses the

unique adaptive nature of ML systems while maintaining regulatory oversight. The FDA has also established Good Machine Learning Practice (GMLP) principles in collaboration with Health Canada and MHRA, providing foundational guidance for AI device development.(16,17)

3.3 European Union (MDR) Framework

The European Union's Medical Device Regulation (EU) 2017/745, which became fully applicable in May 2021, establishes a four-class system (Class I, IIa, IIb, III) for medical devices including AI/ML-based software. Software intended to provide information for diagnostic or therapeutic decisions is subject to specific classification rules under Rule 11 of Annex VIII.(18,19) The EU AI Act, which entered into force in August 2024, further classifies AI systems in regulated medical products as "high-risk," triggering additional compliance requirements including risk management systems, data governance protocols, and quality management systems.(Kalodanis et al., 2025)(21)

The intersection of MDR and AI Act requirements creates a comprehensive but complex regulatory environment. AI medical devices must comply with both the safety and performance requirements of the MDR and the AI-specific obligations of the AI Act, including algorithmic transparency, bias mitigation and human monitoring provisions. This dual framework provides robust patient protection but may create compliance challenges for manufacturers.(22)

3.4 Japan (PMDA) Framework

Japan's Pharmaceuticals and Medical Devices Agency (PMDA) have established a dedicated SaMD Office to address the unique regulatory challenges of software-based medical devices. The PMDA utilizes a four-class classification system (Class I, II, III, IV) and has implemented a "Two-Step Approval Process" specifically designed for SaMD devices. Under this innovative approach, devices demonstrating efficacy can receive First-Step approval for market entry, with Second-Step approval granted upon establishment of clinical benefit through real-world use.(23)

As of July 2024, PMDA had approved over 460 SaMD devices, including 312 programs for computer-assisted imaging diagnostics, 79 for non-imaging computer-assisted diagnostics, and 59 for therapy planning support.(24) The PMDA's "Dash for SaMD" project aims to reduce approval times while maintaining safety standards, reflecting Japan's commitment to facilitating access to innovative digital health technologies.(25)

3.5 Canada (Health Canada) Framework

Health Canada regulates AI/ML-enabled medical devices through guidance documents on Software as a Medical Device (SaMD)(26,27) and specific guidance for Machine Learning-Enabled Medical Devices (MLMD).(28) The Canadian framework emphasizes the entire product lifecycle, requiring manufacturers to address Good Machine Learning Practice (GMLP), design documentation, risk management, data selection and management, development and training, testing and evaluation, clinical validation, transparency and post-market monitoring.(29)

A distinctive feature of Health Canada's approach is the emphasis on Predetermined Change Control Plans (PCCPs), which allow manufacturers to pre-authorize certain post-market changes without requiring license amendments. This framework significantly reduces ongoing regulatory burden while ensuring that algorithmic modifications maintain safety and effectiveness. Health Canada also places particular emphasis on data quality and bias mitigation, requiring datasets to be representative of the Canadian population.(30)

3.6 United Kingdom (MHRA) Framework

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has established a Software Group specifically dedicated to ensuring the safety and regulatory compliance of Software as a Medical Device (SaMD) and AI as a Medical Device (AIaMD).(31) The MHRA's Software and AI as a Medical Device Change Programme Roadmap, published in October 2022, outlines comprehensive reforms to the regulatory framework for digital health technologies.(32,33)

The MHRA has collaborated with the FDA and Health Canada to establish international regulatory principles for AI in medical devices, including Good Machine Learning Practices (GMLP) and Predetermined Change Control Plans (PCCPs).(15,34) The agency is actively refining classification frameworks and plans to up-classify AI-enabled devices from Class I to higher risk categories, reflecting the unique risks associated with AI technologies. The UK framework also addresses post-market surveillance through the Yellow Card Scheme for adverse event reporting.(35,36)

3.7 Australia (TGA) Framework

Australia's Therapeutic Goods Administration (TGA) regulates medical devices through a four-class risk-based classification system (Class I, IIa, IIb, III). Software is classified based on clinical significance and potential harm, with higher classifications requiring assessment by the TGA or a recognized conformity assessment body. The TGA has published specific guidance on Software as a Medical Device to assist manufacturers in navigating the regulatory requirements.(37,38)

The Australian framework emphasizes factors such as intended use, level of invasiveness, duration of contact with the body, and overall risk to patient health in determining device classification. Higher-risk devices require more extensive technical documentation, quality management system certification, and clinical evidence. The TGA's approach aligns closely with the EU MDR framework, facilitating mutual recognition

agreements and streamlined market access for manufacturers.(39,40)

The TGA has been proactive in addressing the unique challenges posed by AI-based medical devices, incorporating principles from the IMDRF guidance into its regulatory approach. The agency recognizes that software-based devices require different regulatory considerations than traditional hardware devices, particularly regarding continuous learning capabilities and algorithm updates. Australia's regulatory framework emphasizes post-market surveillance to ensure ongoing safety and effectiveness of AI devices in clinical use.(41)

3.8 India (CDSCO) Framework

India's Central Drugs Standard Control Organisation (CDSCO) released comprehensive draft guidance for medical device software in October 2025, marking a significant advancement in the regulation of AI-based medical devices in India. (42) The guidance distinguishes between Software in a Medical Device (SiMD) and Software as a Medical Device (SaMD), establishing a four-class risk classification system (Class A, B, C, D) based on the significance of information provided and the severity of the medical condition addressed.(43)

The Indian framework introduces several innovative provisions, including the Algorithm Change Protocol (ACP) requirement for AI/ML devices, which mandates manufacturers to specify how algorithmic updates will be managed, validated and reported.(44) The guidance aligns with international standards including ISO 13485,(45) ISO 62304,(46) and IMDRF recommendations, demonstrating India's commitment to global harmonization.(47) Licensing pathways vary by risk class, with Class A and B devices regulated by State Licensing Authorities and Class C and D devices requiring Central Licensing Authority approval.(48)

CDSCO's approach represents a significant advancement in regulating medical software in India, providing much-needed clarity for manufacturers and developers. The guidance addresses the complete software lifecycle from design and development to post-market surveillance, ensuring that AI-based medical devices meet appropriate safety and efficacy standards. The framework also emphasizes the importance of quality management systems and risk management throughout the device lifecycle, aligning with international best practices.(49)

3.9 Proposed Unified Classification System

Based on the comparative analysis of existing frameworks, we propose a unified four-tier risk classification system that harmonizes disparate regulatory approaches while accommodating regulatory authority’s specific requirements. The proposed framework integrates the IMDRF SaMD risk categorization matrix with practical regulatory pathways from major jurisdictions. This unified system aims to address the current regulatory fragmentation that creates significant barriers to global market access for innovative AI medical technologies while ensuring appropriate patient safety protections.

The development of this unified framework involved extensive analysis of the strengths and limitations of existing regulatory systems. Key considerations included the need for a clear and intuitive classification structure, alignment with internationally recognized standards, flexibility to accommodate emerging technologies, and practicality for both regulators and manufacturers. The proposed system builds upon the IMDRF SaMD framework, which has gained widespread international acceptance while incorporating practical insights from the implementation experiences of major regulatory authorities.

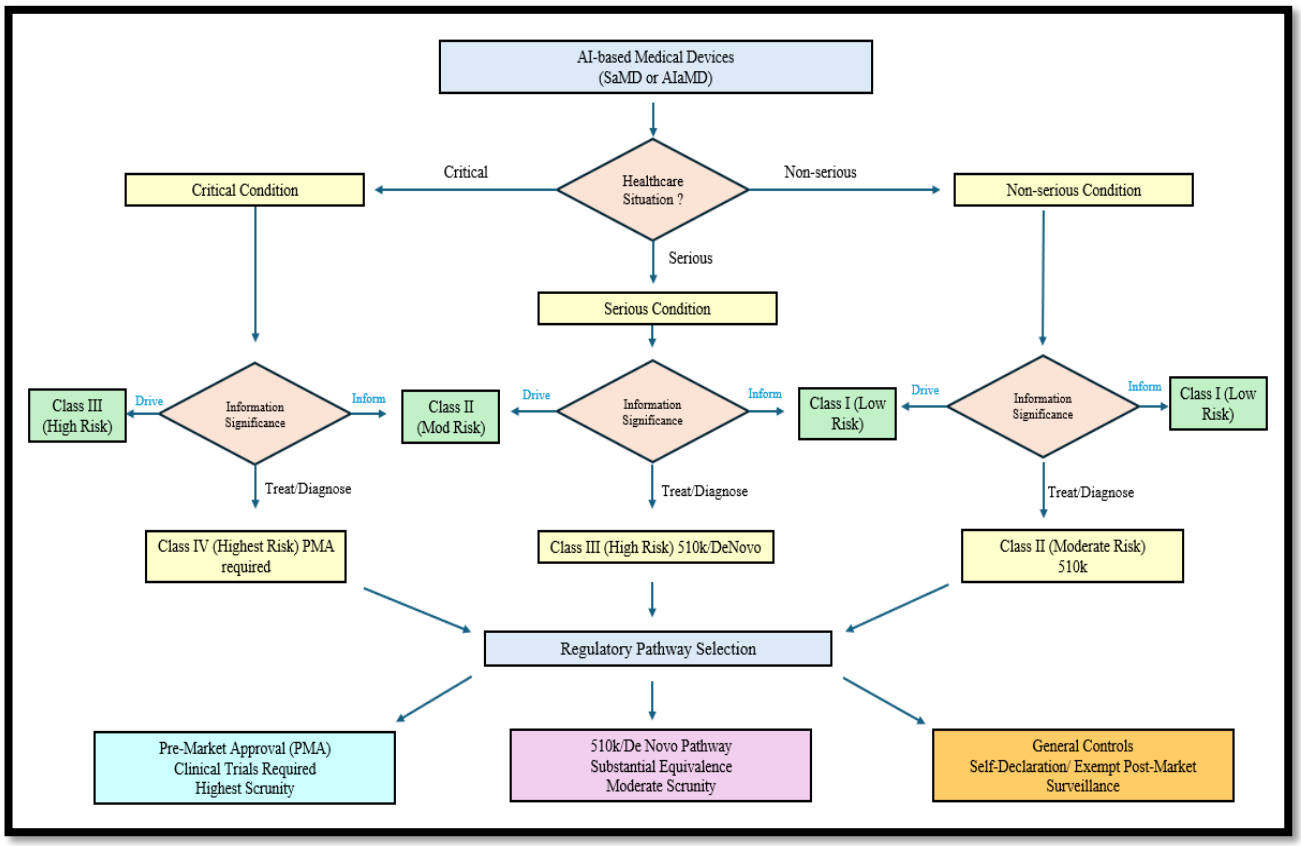

Figure 1. Proposed Unified Classification System for AI-Based Medical Devices

3.10 Framework Components

The proposed unified classification system is structured around two primary decision dimensions that together determine the risk classification and corresponding regulatory pathway for AI-based medical devices. These dimensions were selected based on their demonstrated utility in existing regulatory frameworks and their alignment with the fundamental principles of risk-based regulation.

Healthcare Situation Severity: This dimension categorizes the medical condition based on potential patient impact. Critical conditions are those that are life-threatening and require immediate intervention, where device malfunction could result in death or serious permanent harm. Serious conditions are non-life-threatening but represent significant health concerns where mismanagement could cause substantial harm or prolonged suffering. Non-Serious conditions are minor health concerns with limited potential for patient harm, where device errors would have minimal clinical consequences. This three-tier severity scale provides sufficient granularity for risk stratification while remaining intuitive for manufacturers and regulators.(50)

Information Significance: This dimension characterizes the role of software output in clinical decision making. Treat/Diagnose represents the highest level of significance, where the software directly provides diagnostic conclusions or treatment recommendations that drive patient management decisions. Drive indicates that the software actively influences clinical management through alerts, prioritization, or recommendations that guide healthcare provider decisions. Inform represents the lowest level of significance, where the software provides information for consideration without directly influencing clinical decisions. This dimension recognizes that the same clinical information can have different risk implications depending on how it is used in the care process.(51)

The intersection of these two dimensions creates a nine-cell matrix that maps to four risk classes. This approach provides a systematic and transparent method for classification that reduces subjectivity and promotes consistency across countries. The framework also includes provisions for special considerations, such as when software is used in combination with other devices or when the intended use of population includes vulnerable groups requiring additional safeguards.

Table 2: Unified Risk Classification Matrix

Healthcare Situation	Inform	Drive	Treat/Diagnose

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Healthcare Situation	Inform	Drive	Treat/Diagnose
Non-Serious	Class I	Class I	Class II
Serious	Class II	Class II	Class III
Critical	Class III	Class III	Class IV

3.11 Regulatory Pathway Mapping

Each risk class in the unified system maps appropriate regulatory pathways that balance patient safety with innovation facilitation. The pathway mapping draws from best practices across regulatory bodies while providing a consistent structure that manufacturers can apply globally. This approach reduces regulatory complexity and enables more efficient market access strategies.

Class I (Low Risk): Devices in this category are subject to general controls and may be exempt from premarket review or eligible for self-declaration.(52) Manufacturers must maintain quality management systems and comply with essential safety requirements. Post-market surveillance requirements include basic adverse event reporting and complaint handling procedures. The regulatory burden is intentionally minimized for these low-risk devices to encourage innovation in wellness and general health information applications. Examples include wellness apps that track general health metrics, medication reminders, and basic health information tools that do not claim to diagnose or treat specific conditions.(53,54)

Class II (Moderate Risk): Devices require 510(k) premarket notification or equivalent moderate scrutiny pathway, demonstrating substantial equivalence to a legally marketed predicate device or meeting special controls established for the device type. Clinical validation data must demonstrate that the device performs as intended with acceptable accuracy and reliability.(55) Quality management system certification to ISO 13485 is typically required. Post-market surveillance includes systematic complaint handling, adverse event reporting, and periodic safety monitoring. This class represents the majority of AI-based medical devices currently on the market, including AI-assisted diagnostic support tools for non-critical conditions, clinical decision support systems that provide recommendations but do not replace clinician judgment and monitoring applications for stable chronic conditions.(56)

Class III (High Risk): Devices require De Novo classification or enhanced 510(k) review with specific controls when no appropriate predicate exists. Robust clinical evidence is required, including prospective validation studies that demonstrate the safety and effectiveness of the device in its intended use population. Predetermined Change Control Plans (PCCPs) are mandatory for AI/ML devices to ensure that algorithm updates maintain safety and effectiveness.(57) Quality management systems must address the full AI/ML lifecycle, including data management, model development, validation, and deployment. Post-market surveillance requirements are more stringent, including periodic safety update reports and active monitoring for algorithmic performance drift. Examples include AI systems for diagnosing serious conditions such as cancer or heart disease, treatment planning systems for complex medical conditions and monitoring systems for patients at high risk of deterioration.(58)

Class IV (Critical Risk): Devices require Pre-Market Approval (PMA) or equivalent highest scrutiny pathway, including extensive clinical trials demonstrating safety and effectiveness with reasonable assurance.(59) These devices support or sustain human life and present the highest potential risk. Continuous monitoring, periodic safety updates, and stringent algorithm change protocols are mandatory. Manufacturing facilities are subject to pre-approval inspection, and any modifications require prior regulatory approval. Real-world evidence collection may be required as a condition of approval. Examples include AI systems for diagnosing or treating life-threatening conditions where errors could result in death or serious harm, autonomous diagnostic systems that operate without clinician oversight in critical care settings, and AI-driven treatment systems that directly control therapeutic interventions for life-threatening conditions.(60)

3.12 Comparative Analysis of Regulatory Requirements

The graphs (Figure 2(a-d)) provide comparative analysis of regulatory frameworks across regulation authorities, highlighting areas of convergence and divergence that informed the development of the unified classification system. The analysis reveals both the common foundations that support harmonization and the specific differences that must be addressed. They provide a comparative overview of global regulatory frameworks for medical devices, with a particular focus on risk classification, approval pathway complexity, AI/ML-specific requirements, and approval timelines across major regulatory authorities.

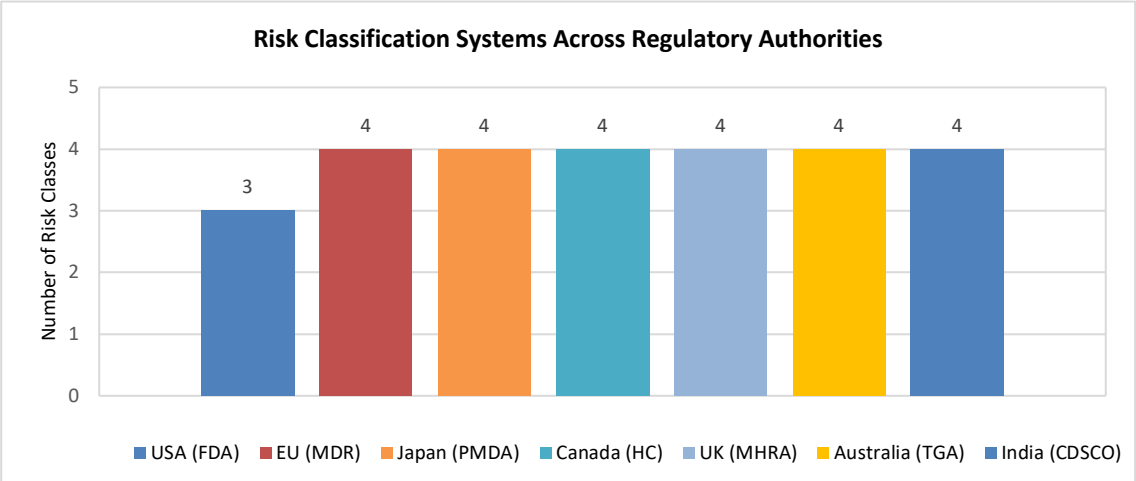

Figure 2(a). Comparison of the number of medical device risk classes across major regulatory authorities

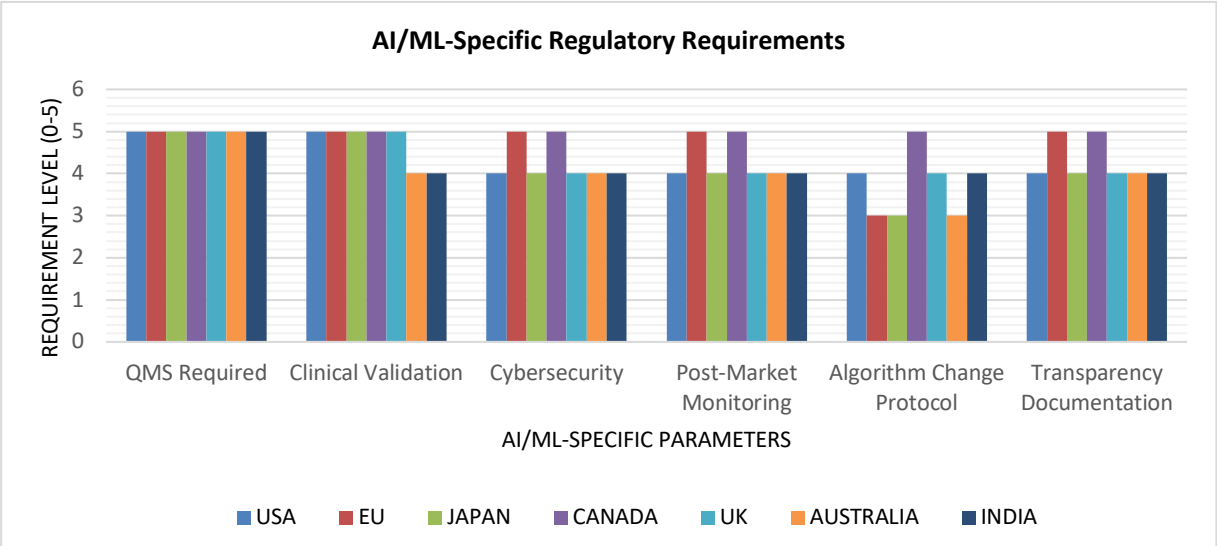

Figure 2(b). Evaluation of AI/ML-specific regulatory requirements across countries

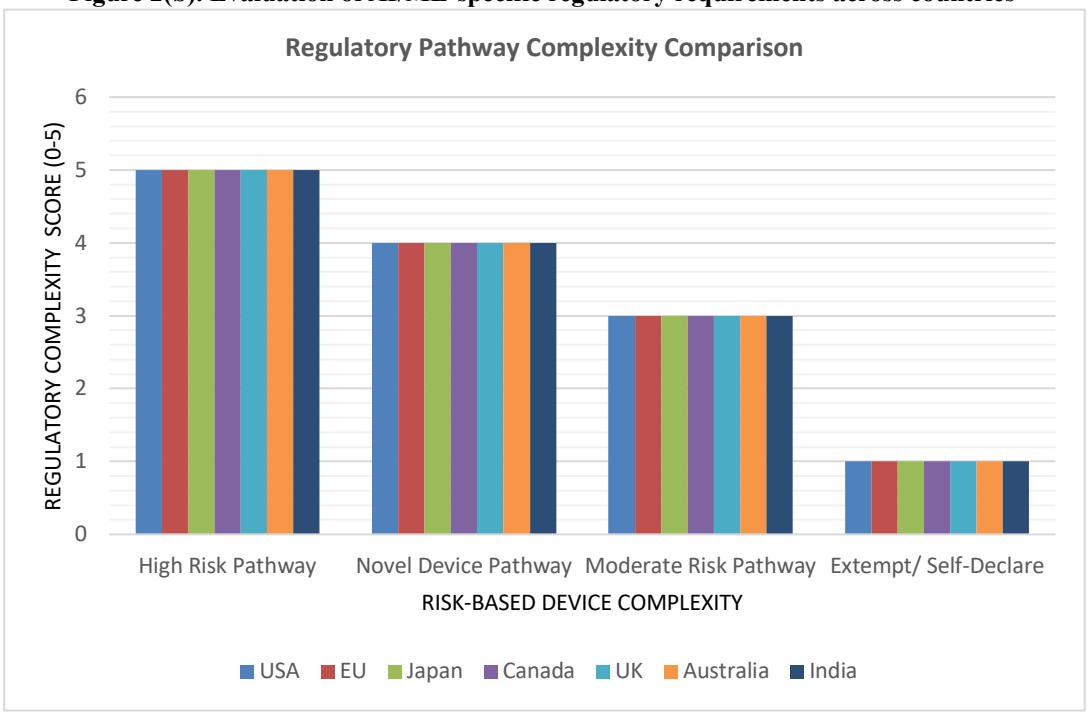

Figure 2 (c). Comparative assessment of regulatory pathway complexity (scale 0–5) across USA, EU, Japan, Canada, UK, Australia and India highlighting increasing complexity from exempt/self-declaration pathways to high-risk PMA approvals.

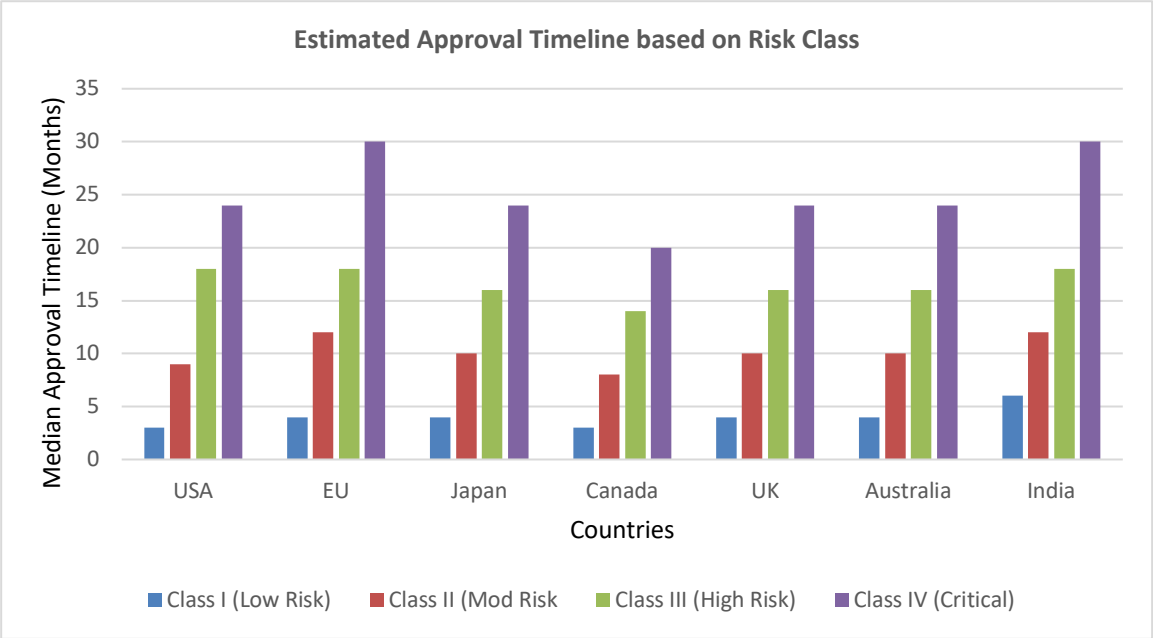

Figure 2(d). Comparison of estimated approval timelines based on risk class of medical device

3.13 Implementation Considerations

Implementing a unified classification system across multiple regulatory bodies requires careful consideration of practical, legal, and administrative factors. While the proposed framework provides a conceptual foundation for harmonization, successful implementation will require sustained commitment from regulatory authorities, industry stakeholders, and international organizations.

Legal and legislative frameworks in each regulatory agency may require modification to accommodate unified classification principles. Some regulatory agencies have statutory requirements that specify particular classification approaches, which may need legislative amendment to implement harmonized systems. Regulatory authorities should assess the legal feasibility of adopting unified framework elements and identify any statutory barriers that may require address.

Administrative capacity and resource constraints must also be considered. Implementing new classification systems requires training for regulatory staff, updates to submission systems and processes, and communication with regulated industry. Jurisdictions with limited regulatory resources may require phased implementation approaches or technical assistance from international partners. The transition period for implementing unified frameworks should be carefully planned to minimize disruption to ongoing regulatory activities.

Industry readiness and stakeholder engagement are critical success factors. Manufacturers must have sufficient notice to adapt their regulatory strategies and submission preparations to new classification systems. Early and ongoing engagement with industry associations, professional societies, and patient advocacy groups can help identify implementation challenges and build support for harmonization efforts. Pilot programs or voluntary adoption phases may facilitate smooth transition to unified frameworks.

Our comparative analysis reveals several important findings that inform the proposed unified framework and provide insights into the current state of AI medical device regulation globally.

Convergence on Risk-Based Approaches: All regulatory bodies have adopted risk-based classification systems, recognizing that regulatory scrutiny should be proportional to potential patient harm. This fundamental convergence provides the foundation for harmonization efforts. While the number of risk classes varies, the underlying principle that higher-risk devices require more stringent oversight is universally accepted. This convergence reflects the influence of the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF), in promoting harmonized regulatory approaches.(61,62)

IMDRF Framework Adoption: The IMDRF SaMD risk categorization framework has gained widespread international acceptance as a conceptual foundation, though implementation varies across regulatory agencies. The two-dimensional risk matrix (healthcare situation x information significance) provides a robust analytical tool that transcends specific regulatory systems. However, the translation of IMDRF categories into specific regulatory requirements remains jurisdiction-specific, creating the need for the

unified pathway mapping proposed in this framework.(63,64)

AI/ML Specific Requirements: Jurisdictions are increasingly developing AI-specific regulatory provisions, including Predetermined Change Control Plans (PCCPs), Good Machine Learning Practice (GMLP) requirements, and algorithmic transparency obligations.(65) Canada leads in comprehensive AI lifecycle requirements with its detailed MLMD guidance. The FDA, Health Canada, and MHRA collaboration on GMLP principles represents an important step toward international harmonization of AI development standards. However, requirements for algorithm validation, bias assessment, and performance monitoring vary significantly across regulatory authorities.(66)

Post-Market Surveillance: All regulatory authorities emphasize post-market surveillance for AI devices, recognizing the need to monitor real-world performance and detect algorithmic drift or bias.(67) The EU's combination of MDR and AI Act requirements creates the most comprehensive post-market framework, with mandatory periodic safety update reports and specific obligations for AI system monitoring. The FDA's approach to real-world performance monitoring is evolving, with increasing emphasis on post-market studies for AI devices. The challenge of monitoring continuously learning algorithms remains an area of active regulatory development across all regulatory authorities .(68)

Cybersecurity Integration: Cybersecurity requirements are increasingly integrated into AI medical device regulation, with Health Canada and the EU requiring explicit cybersecurity documentation as part of pre-market submissions. FDA data shows cybersecurity mentioned in only 54% of 2024 ML device approvals, indicating ongoing development in this area. The interconnected nature of AI systems, which often rely on cloud infrastructure and data networks, creates unique cybersecurity challenges that traditional medical device regulations were not designed to address. Jurisdictions are responding with updated guidance, but comprehensive cybersecurity frameworks for AI medical devices remain under development.(69)

Data Quality and Bias Mitigation: A growing emphasis on data quality and bias mitigation is evident across regulatory authorities, reflecting concerns about AI algorithm performance across diverse patient populations. Health Canada explicitly requires datasets to be representative of the Canadian population, while the EU AI Act mandates assessment of potential biases that could affect health and safety.(70) The FDA has issued guidance on clinical trial diversity, and the IMDRF has published guidance on SaMD bias evaluation. These developments indicate a shift toward more rigorous evaluation of AI training data and algorithmic fairness.(71)

Transparency and Explainability: Transparency and explainability requirements emerging as key regulatory themes, particularly in the EU AI Act, which mandates that high-risk AI systems be designed to enable users to interpret system outputs. The IMDRF has emphasized the importance of transparency in SaMD labeling and instructions for use. However, the practical implementation of explainability requirements for complex deep learning models remains challenging, and specific regulatory expectations vary across regulatory authorities. This area is likely to see continued development as the field of explainable AI matures.(72,73)

4. Conclusion

This research has presented a comprehensive comparative analysis of AI medical device regulatory frameworks across seven major regulatory authorities and proposed a unified four-tier risk classification system. The proposed framework integrates the IMDRF SaMD risk categorization matrix with practical regulatory pathways, providing a common language for international harmonization while accommodating jurisdiction-specific requirements.

The unified classification system categorizes AI medical devices into Class I (Low Risk), Class II (Moderate Risk), Class III (High Risk), and Class IV (Critical Risk) based on healthcare situation severity and information significance. This framework addresses the current regulatory fragmentation that creates barriers to global market access for innovative AI medical technologies. Based on our analysis, we offer the following recommendations for stakeholders across the healthcare ecosystem. These recommendations are designed to promote the adoption of harmonized regulatory approaches while addressing the practical needs of different stakeholder groups. The unified classification system proposed in this paper provides a foundation for these collaborative efforts, offering a practical framework that respects regulatory authorities' differences while promoting convergence on essential safety and effectiveness standards. We encourage regulatory authorities, manufacturers, and healthcare stakeholders to engage with this framework, provide feedback on its practical application, and contribute to the ongoing evolution of AI medical device regulation. Only through such collaborative engagement can we achieve the dual goals of protecting patient safety and fostering innovation in this rapidly advancing field.

5. Limitations

This study has several limitations that should be acknowledged. The regulatory landscape for AI medical devices is evolving rapidly, and frameworks analyzed may have been updated since data collection. Regulatory authorities frequently issue new guidance documents, update existing requirements, and implement policy changes that may not be reflected in this analysis. Readers should consult current regulatory sources for the most up-to-date requirements in each regulatory authority.

The proposed unified system represents a conceptual framework that requires validation through stakeholder consultation and pilot implementation. While the framework is based on thorough analysis of existing systems and established regulatory principles, its practical effectiveness can only be confirmed through real-world application. The translation of the framework into specific regulatory requirements in different legal and administrative contexts would require additional adaptation and refinement.

Additionally, the study focused on seven major regulatory authorities with well-established regulatory systems for medical devices. Regulatory approaches in other important markets, including China, Brazil, South Korea, and emerging markets, were not included in this analysis. These regulatory authorities may have different regulatory philosophies, resource constraints, and healthcare system characteristics that influence their approaches to AI medical device regulation. A more comprehensive global analysis would provide additional insights for harmonization efforts.

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