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Comparative Analysis of Medical Device Regulation in Korea and the United States

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Abstract

Purpose: This study aims to compare the medical device classification systems and regulatory frameworks of Korea and the United States. By analyzing ten comparable device categories and adverse event reports, it examines the effectiveness and safety management levels of each country's regulatory system. **Research Design, Data, and Methodology:** This study conducted a comparative analysis using official regulatory and statistical data. In Korea, data were obtained from the MFDS and NIDS, while in the United States, FDA's MAUDE database was used. Population data from Statistics Korea were applied to calculate adverse event rates per total population. **Results:** A comparative analysis across 10 device categories revealed that the MFDS generally assigned a risk classification 1 class higher than the FDA for generally equivalent devices. From 2020 to 2024, the number of adverse reaction reports for Korean medical devices increased slightly by 3.2% (from 8,838 to 9,122), while the United States saw a 67% increase (from 1,567,545 to 2,628,663). In 2024, the adverse reaction reporting rate in the United States was approximately 40 times that of Korea. **Conclusion:** Research findings indicate that Korea's Class 4 regulatory framework is stricter than the U.S. Class 3 system in terms of ensuring safety and efficacy, resulting in a significantly lower number of adverse event reports. These results suggest that Korea's medical device regulations exert a certain degree of influence on industrial reliability and patient safety. This provides meaningful implications for future policy improvements and institutional development within the medical device industry.

Keywords : Adverse Event, Medical Device, Medical Device Classification, Safety, Regulation

JEL Classification Code : I00,I10,I11, I18, I19

1. Introduction

The medical device industry is growing rapidly worldwide due to factors such as an aging population, increasing chronic diseases, the spread of infectious diseases, and the rapid advancement of digital healthcare technologies (Choi, 2025; Kwon & Gal, 2025; Kang, 2025). The domestic medical device market size, encompassing both production and imports/exports, expanded from approximately 13.7 trillion won in 2017 to about 29.5 trillion won in 2021,

recording an average annual growth rate of approximately 7.2% (KHIDI Health Industry White Paper, 2023). Furthermore, according to data from the Ministry of Food and Drug Safety (MFDS), the number of medical device approvals was 8,269 in 2019, 8,183 in 2020, 7,060 in 2021, 6,767 in 2022, and 7,065 in 2023 (Statistics MFDS). Although a temporary decline was observed during the COVID-19 pandemic, the number of approvals across all grades of medical devices in Korea has shown an increasing trend since the pandemic.

Particularly since the COVID-19 pandemic, demand for medical devices used in diagnosis, monitoring, and treatment has surged, heightening concerns about the safety and quality control of these devices (Kim, 2024). As medical devices are products used directly on the human body, failure to ensure their safety and efficacy can cause serious harm. Consequently, countries are continuously strengthening their legal and institutional development efforts to systematically manage medical devices (Lee et al., 2021).

Medical device regulation is more than mere regulation; it is a key element in ensuring product quality and reliability, and further serves to establish a foundation for the industry's sustainable growth. From this perspective, the United States and Korea have each built medical device management systems tailored to their respective healthcare environments and industrial conditions.

In the case of the United States, the need for medical device safety management emerged following the Dalkon Shield contraceptive device incident in the early 1970s (Darrow et al., 2021; Shah et al., 2023). This incident resulted in adverse events and fatalities due to inadequate quality control. Consequently, the U.S. Food and Drug Administration (FDA) Act was amended in 1976, and the Medical Device Amendments were enacted. Consequently, the FDA introduced a 3 Class classification system (Class I–III) based on the risk level of medical devices. Pre-market approval requirements (such as Section 510(k) Premarket Notification, 510(k) and Premarket Approval, PMA) and post-market surveillance requirements were specified for each class (Kim, 2014; Sorenson & Drummond, 2014; Lu et al., 2025). This system became a representative model of risk-based management and subsequently influenced medical device legislation in other countries (Lee et al., 2010).

Initially, Korea managed and operated medical devices as part of the Pharmaceutical Affairs Act (Choi et al., 2014). However, as the medical device industry grew into an independent sector and products incorporating diverse technologies emerged, limitations arose in effectively addressing these developments under the existing classification system.

Consequently, the Medical Device Act was enacted in 2003, separating and establishing medical devices as an independent category (Choi, 2020).

This enabled the establishment of a system for the approval, review, and post-market surveillance of medical devices, centered around the MFDS.

Furthermore, Korea has continuously strengthened its alignment with international standards, developing its regulatory framework to a global level. Both the United States and Korea operate risk-based medical device classification systems, but there are differences in the details, such as classification criteria, approval procedures, post-market surveillance systems, and adverse event reporting systems (Son et al., 2023).

Therefore, this study aims to compare and analyze the differences in the medical device classification systems and regulatory frameworks between Korea and the United States. It further examines the effectiveness and safety management levels of each country's regulatory system through a comparative analysis of 10 similar medical device items and an analysis of adverse event reporting rates. This study aims to contribute to exploring institutional improvement directions for enhancing the global competitiveness of Korea's medical device industry while ensuring a balanced guarantee of safety and efficacy.

The objectives of this study are as follows:

1. To compare and analyze the differences in the medical device classification systems by product category between Korea and the United States.

2. To analyze the incidence of adverse events (adverse incidents) associated with medical devices relative to the total population in Korea.

3. To analyze the incidence of adverse events (adverse incidents) associated with medical devices relative to the total population in the United States.

2. Literature Review

Medical device classification in both the United States and Korea categorizes devices based on their potential impact on the human body. As shown in Table 1, the MFDS classifies devices into four classes ranging from Class 1 (Minimal potential risk) to Class 4 (High potential risk). The FDA classifies devices into three classes ranging from Class I (low to moderate risk) to Class III (high risk) (Cha, 2023; Park, 2023). Accordingly, MFDS follows these approval procedures: Class 1 requires notification, Class 2 and 3 require certification and approval, and Class 4 requires approval. However, the FDA has a somewhat more complex approval system, primarily involving three procedures: De Novo Classification Request, Premarket Notification 510(k), and Premarket Approval (PMA) (Aboy et al., 2024). For the

FDA's De Novo Classification Request, if a Class 1 or Class 2 device has demonstrated safety and effectiveness but no such device is currently marketed, this procedure is used for preliminary classification. If a device of the same classification is already marketed, the Clearance Process is pursued via 510(k). Finally, for Class 3 devices, marketing authorization is obtained through the Premarket Approval (PMA) process, enabling the device to be marketed (Choe & Choi, 2024; Lim & Song, 2018).

To verify adverse event cases involving medical devices, credible statistics from each country are required. In Korea, the National Institute of Drug Safety and Risk Management (NIDS), a public institution and subsidiary of the MFDS, performs certification activities for most Class 1 devices and some Class 2 devices under the MFDS's medical device licensing system. NIDS publishes trends in medical device safety information reporting by investigating adverse event cases through its Medical Device Adverse Event Evaluation Committee and assessing causality.

The U.S. FDA requires the tracking and reporting of adverse events through its postmarket surveillance system (Knisely et al., 2020; Liao et al., 2024; Mishali et al., 2025). It publishes Medical Device Reports (MDRs), including adverse event cases, in the Manufacturer and User Facility Device Experience (MAUDE) database and provides data spanning over 10 years.

Table 1: FDA and MFDS Medical Device Classification System

Category	MFDS	FDA
Rating Classification	**4-Class system** Class 1: Minimal potential risk Class 2: Low potential risk Class 3: Moderate potential risk Class 4: High potential risk	**3-Class system** Class I (low to moderate risk): general controls Class II (moderate to high risk): general controls and Special Controls Class III (high risk): general controls and Premarket Approval (PMA)
Certification and Licensing Procedures	Class 1: Registration Class 2: Certification (3rd party) Class 3 and 4: Approval (MFDS review)	Class I: Registration Class II: 510K Premarket Notification Class III: Premarket Approval (PMA)

3. Research Methods

Medical device classification varies by country's standards. For Korea, we referenced the MFDS regulations on medical device classification by category. Among the more than 2,000 medical device categories (Yoo et al., 2010), we excluded Korean Class I devices, which are highly subdivided and considered to pose minimal risk to the human body. From Class II and higher devices, we selected items for which the regulatory definitions of Korea and the United States were consistent. In addition, we focused on medical devices and supplies commonly used in hospital settings, where patient safety is considered critical. For the United States, classification information was retrieved from all FDA medical device databases.

Additionally, total population statistics for Korea and the United States from 2020 to 2024 were obtained from Statistics Korea to compare adverse event rates by classification level. For adverse event cases, Korea's data were analyzed using publicly available NIDS data, while the United States' data were analyzed using the FDA's MAUDE database for the years 2020 to 2024.

4. Results and Discussion

4.1. Medical device classification systems by product category between Korea and the United States.

As shown in Table 2, when comparing 10 categories of medical devices between Korea and the United States, it can be confirmed that Korea tends to apply a higher classification level than the United States for the same device category. For example, gamma cameras, stethoscopes, medical thermal sterilizers, taste testers, umbilical cord clamps, and absorbable body staples are classified as Class 2 by the MFDS, whereas the FDA classifies them as Class 1, assigning a higher classification than the Korean medical device market. Particularly in the U.S., there are cases where the 510(k) premarket notification procedure, corresponding to Korea's Class 2 and Class 3 certification approvals, is exempted, showing a different approach from the MFDS.

Table 2: Comparison of Medical Device Classification in Korea and the United States

Regulation Number	FDA Regulation Description	Regulation Number	MFDS Regulation Description	FDA Class	MFDS Class
892.1100	Scintillation (gamma) camera	A13110.01	Gamma camera	Class 1	Class 2
870.2390	Phonocardiograph	A26180.01	Phonocardiograph	Class 1	Class 2
872.6710	Boiling water sterilizer	A04030.01	Disinfector, thermal	Class 1	Class 2
874.1500	Gustometer	A30250.01	Gustometer	Class 1	Class 2
880.5950	Umbilical occlusion device	A38020.0x	Umbilical	Class 1	Class 2
880.6375	Patient lubricant	B07150.01	Lubricant for medical use	Class 1	Class 2
880.6820	Medical disposable scissors	A42010.02	Scissors, manually-operated, single-use	Class 1	Class 2
870.3450	Vascular graft prosthesis	B04230.01	Prosthesis, vascular, peripheral	Class 2	Class 3
878.4300	Implantable clip	A38090.09	Clip, surgical, non-biodegradable	Class 2	Class 3
878.4750	Implantable staple	A38170.02	Surgical staple, non-biodegradable	Class 2	Class 3

Note: Table are presented in thousands of persons.

4.2. Comparison of the Total Populations of Korea and the United States

Table 3 shows the results comparing the total population changes in Korea and the United States from 2020 to 2024. Korea's total population decreased slightly from 51,836 thousand in 2020 to 51,751 thousand in 2024, Particularly since 2020, the decline in the working-age population coupled with the rise in the proportion of the super-aged population indicates long-term changes across the entire population structure.

Showing a minimal decrease rate of approximately 0.16% over the five-year period. These results confirm that South Korea has entered a phase of population decline due to the simultaneous progression of low birth rates and super-aging.

However, the total population of the United States increased by approximately 1.8% during the same period, from 339,436 thousand to 345,427 thousand, maintaining a moderate growth trend. Therefore, Korea and the United States exhibit contrasting trends in demographic structure changes over the same period. This is expected to have differing impacts on the future size of the medical device market, healthcare demand, and medical service policies for the elderly.

Table 3: Comparison of Total Population between Korea and the United States (2020–2024)

Year	Korea	United States
2020	51,836	339,436
2021	51,770	340,161
2022	51,673	341,534
2023	51,713	343,477
2024	51,751	345,427

Note: Table are presented in thousands of persons.

4.3. Incidence of Adverse Events of Korea and the United States

Table 4: Incidence of Medical Device Adverse Reactions in Korea and the United States (2020–2024)

Year	Adverse Event Reporting of Korea	Adverse Event Reporting of United States
2020	8,838	1,567,545
2021	7,731	2,031,124
2022	7,440	2,949,901
2023	8,670	2,342,042
2024	9,122	2,628,663

Table 4 presents the results comparing adverse event reporting for medical devices in Korea and the United States. Based on data from the NIDS and the FDA, the trends in adverse events for medical devices from 2020 to 2024 were analyzed. The results show that the number of adverse event reports for medical devices in Korea increased by approximately 3.2%, from 8,838 cases in 2020 to 9,122 cases in 2024 (Statistics NIDS). In the United States, the number increased by approximately 67%, from 1,567,545 cases to 2,628,663 cases during the same period. Both countries showed an increasing trend in the number of reports. However, in terms of growth rate, the United States showed a significantly higher increase than Korea.

Figure 1 shows the ratio of medical device adverse event reports per total population in Korea and the United States. In Korea, the ratio increased slightly from 1.7×10^{-2} (0.017 %) in 2020 to 1.76×10^{-2} (0.0176 %) in 2024. In the United States, the ratio showed a significant increase from 4.62×10^{-1} (0.462 %) to 7.61×10^{-1} (0.761 %) over the same period. In 2021 and 2022, both countries experienced fluctuations in the number of adverse events reports due to the impact of the COVID-19 pandemic, a unique variable, which varied depending on each nation's quarantine policies and

healthcare system conditions.

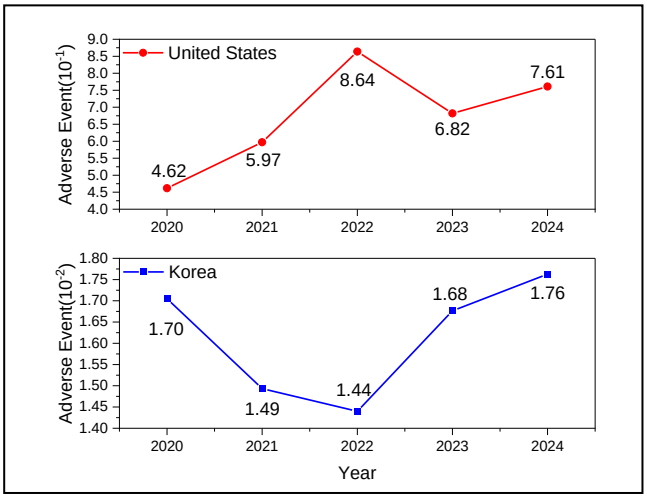

Figure 1: Analysis of Medical Device Adverse Event Rates per Total Population in Korea and the United States

Figure 1 and Table 4, the adverse event cases and rates per reported product were for domestically developed medical devices, not imported products. For medical devices including imported products, the results are shown in Figure 2 and Table 5.

Table 5: Incidence of adverse reactions to domestic and foreign medical devices (2020–2024)

Year	Adverse Event Reporting of Korea	Adverse Reaction Report for Imported Products
2020	8,838	45,066
2021	7,731	63,603
2022	7,440	89,730
2023	8,670	82,499
2024	9,122	107,812

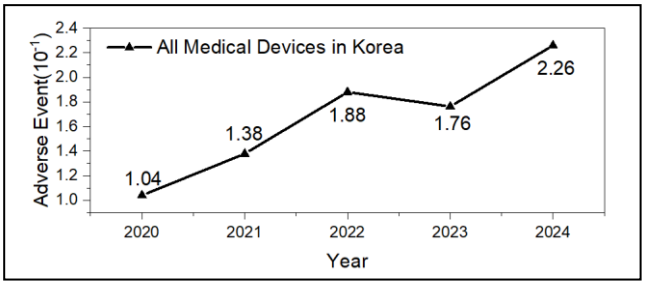

Figure 2: Analysis of the Incidence Rate of Medical Device Adverse Events in Relation to the Total Population for Medical Device Products in Korea

For domestic medical devices, adverse event cases were low. However, adverse event cases including overseas products increased from 1.04×10^{-1} (0.104 %) in 2020 to 2.25×10^{-1} (0.225 %) in 2024. This confirms that adverse event cases for medical devices including overseas products are higher than those for domestic products.

However, adverse event cases involving medical devices, including imported products, have more than doubled from 53,904 cases in 2020 to 116,934 cases in 2024.

Therefore, it can be confirmed that adverse events for Korean medical devices are lower than those for U.S. medical devices. Accordingly, it was confirmed that Korea's regulatory framework aims for stricter safety and efficacy standards.

The adverse event reports from both countries previously investigated are based on data from NIDS and the FDA, and both agencies include reported cases regardless of whether a causal relationship between the medical device and the adverse event has been established.

Therefore, this data cannot necessarily be interpreted as conclusive evidence that the adverse events were directly caused by the medical device in question. Furthermore, various entities including medical device users, manufacturers, and healthcare institutions participate in reporting, and both agencies explicitly state that some duplicate reporting may exist. Consequently, this study acknowledged these limitations and utilized the data as reference material.

5. Conclusions

Korea and the United States have developed their medical device laws and regulatory frameworks within distinct historical and institutional contexts. This has led to differences in the direction of regulatory development and the manner of its application. This study compared and analyzed the medical device classification systems of both countries, identifying differing classification levels across 10 product categories. Korea's classification levels showed a classification approximately one grade higher than the U.S. classification system. Notably, the U.S. Food and Drug Administration (FDA) exempts certain products from the 510(k) clearance procedure, which corresponds to the certification approval process required by Korea's MFDS. Accordingly, Korea's regulatory system appears designed to ensure stricter safety and efficacy guarantees. As of 2024, Korea's maximum adverse event rate was 0.0176 %, more than 40 times lower than the U.S. rate of 0.761 %. The incidence of adverse events for medical devices, including overseas products, is also 0.225%, which is three times lower than that in the United States. These results suggest that South Korea's medical device regulations contribute to enhancing industry credibility and ensuring the safety of medical device users.

However, this study has several limitations. First, This

study only performed comparative analysis on 10 of these categories. Consequently, the findings may be limited in fully representing the entire medical device classification systems of both countries. Second, the adverse event reporting data used in this study contains several uncertainties, including the possibility of duplicate reporting and the causal relationship between the reported adverse events and the adverse events themselves. Therefore, it is difficult to clearly establish a causal relationship between regulatory classification and adverse event incidence using only the data from this study.

Future research should expand the range of medical device categories analyzed and utilize more granular classification data to enhance the generalizability of the findings. Furthermore, subsequent studies applying clear and standardized criteria to the adverse event reporting systems of both countries would enable a clearer understanding of how regulatory differences impact safety outcomes.

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