The Medical Device Industry in Korea: Strategies for Market Entry

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Regulatory

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Summary
The Korean medical device market is growing rapidly and presents excellent opportunities in the area of development and distribution of medical devices. Understanding the device market in Korea is critical to making the best of these opportunities, as is a working knowledge of the device registration and licensing process there. Key steps for getting a device approved by Korea’s Ministry of Food and Drug Safety (MFDS) include 1) Establishing a license holder/distributor in Korea (application for licensing will be through this entity); 2) Testing your product at MFDS-sanctioned laboratories; 3) Submitting a technical file to MFDS (Class III or IV device) or to an MFDS-designated agent (Class II); and 4) Post-approval inspections. Once inspections are complete, product sales can begin.

Medical Device Market
The Korean medical device market is growing at an annual rate of about 13.5% and had a value of $3.9 billion in 2012, making it the third largest medical device market in Asia. In 2013, Korea’s medical device industry reported $2.31 billion in exports and a 1.2% global market share. The Korean government intends to continue increasing medical device exports to a goal of $12.5 billion by 2020, which would represent a 3.8% global market share and would make Korea one of the top 7 countries globally in the medical device space. Medical device approvals by MFDS (formerly the Korea Food and Drug Administration, or KFDA), are also increasing, with 3,100 approved in 2012, a 6.9% year-on-year increase vs 2011. Korea presents unique opportunities for medical device companies due to a population of 49.8 million people who are growing older and whose average income is on the rise.

Medical Device Regulation
The history of medical device regulation in Korea began in 1953 when the Pharmaceutical Affairs Act first defined medical devices and introduced a regulatory system for licensing and product approvals. In 1997, a device classification system with 3 classes was introduced and regulations for good manufacturing practices (GMP) were implemented. The Medical Device Act, passed in 2004, changed the device classification system to accommodate 4 classes (little risk, low risk, medium risk, high risk; see below). Currently, the Medical Device Safety Bureau of MFDS oversees medical device regulation in Korea, while departments within the National Institute of Food and Drug Safety (NIFDS) Evaluation oversee the evaluation and research of medical devices. The general organizational structure of MFDS and NIFDS are provided in Figure 1 and Figure 2. MFDS provides the text of the Medical Device Act, the Enforcement Decree of the Medical Device Act, and the Enforcement Regulations of the Medical Device Act on their website. They also publish news, notices, and amendments pertaining to the Medical Device Act.
Figure 1. Korea MFDS Organizational Structure
Device Types & Classifications

According to the Medical Device Act, a medical device is defined as an instrument, machine, device, material, or any other similar product specified below as one used, alone or in combination, for humans or test studies:

1. A product used for the purpose of diagnosing, curing, alleviating, treating, or preventing a disease.
2. A product used for the purpose of diagnosing, curing, alleviating, or correcting and injury or impairment.
3. A product used for the purpose of testing, replacing, or transforming a structure or function.
4. A product used for birth control.

Drugs and quasi-drugs under the Pharmaceutical Affairs Act and prosthetic limbs and assistive devices for persons with disabilities under Article 65 of the Act on Welfare of Persons with Disabilities are excluded.
Medical devices can be classified into 1 of 3 main types and 4 classes:

- **Product Types**
  - **New (novel) product:** a medical device that is not equivalent to an approved medical device in the purpose of use, working mechanism, or raw materials.
  - **Improved product:** a medical device that is equivalent to an approved medical device in the purpose of use, working mechanism, or raw materials, but not equivalent in performance, test specifications, instructions for use, etc.
  - **Equivalent product:** a medical device that is equivalent to an approved medical device in the purpose of use, working mechanism, raw materials, performance, test specifications, and instructions for use.

- **Product Classifications**
  - **Class I:** medical devices with little potential risk
  - **Class II:** medical devices with low potential risk
  - **Class III:** medical devices with medium serious potential risk
  - **Class IV:** medical devices with high risk

**Device Testing**

As mentioned above, device companies will need to designate a local license holder/distributor and have their products or products tested at MFDS-designated labs in Korea. In most cases foreign test reports can be accepted for biocompatibility, but they must be conducted under Good Laboratory Practices (GLP) for them to be eligible. Electronic medical devices require 4 types of testing: 1) electromagnetic safety, 2) IEC60601-1 test (3rd edition will be applied starting July, 2015), 3) testing to determine type, and 4) performance testing. For manufacturers/distributors entering Korea for the first time, MFDS inspects all products except Class I devices, and even some of those may be inspected for manufacturing. In the case of new (novel) products, clinical trial data will be required and/or clinical evaluation reports citing published clinical trials of equivalent devices.

**Premarket Registration Process**

The process for medical device approval in Korea involves 2 types of technical document review. A General Technical Document Review (TDR) is sufficient for devices that are considered to be substantially equivalent to previously approved products. A more detailed Safety and Efficacy Review (SER) is required for novel devices or devices with new performance, new structure, new purpose for use, or significant differences from previously approved devices that affect safety and effectiveness. Clinical study data are essential for SERs.
Figure 3. MFDS Medical Device Notification and Permission Processes

**CLASS I**
- Product notified as equivalent

**CLASS II**
- Equivalent, improved product
- New product

**CLASS III**
- Technical documents target
- Clinical study targets

- KiFDA auto-registration by online submission
- Certificate of Medical Device Notification will be made available online
- KiFDA System (Electronic window for civil petitions)
- Application and issuance of review results notification
- Application and approval within 10 days
- Application and approval within 80 days
- Application and approval within 65 days
- Application and approval within 80 days
- Application and approval within 80 days
Class II, III, and IV products require permission gained through an approval process. This requires applications for a technical document review and for a certificate of product approval to be submitted to MFDS. The applications may be submitted together as a Package Application or separately as a Sequential Application. Class I devices require notification through an online submission via the KiFDA system, an electronic window for civil petitions. The manufacturer or importer would auto-register through the online submission process and a certificate of Medical Device Notification from MFDS will be made available online. The KiFDA system only applies to medical devices. Devices that require the previously mentioned permission process may not use this online submission program. Figure 3 provides a summary of the permission and notification processes.

General Prohibitions
The Medical Device Act prohibits certain activities relating to the handling of medical devices that are unapproved, altered, unsanitary, or contaminated, and regarding fraudulent advertisement of devices including:

- Repairing, distributing, leasing, providing, or using a medical device without obtaining a permit or filing a report
- Manufacturing, importing, repairing, storing, or displaying a medical device with the intent to distribute, lease, provide, or use it unless done so in accordance with the procedure and method prescribed by Ordinance of the Ministry of Health and Welfare
- Manufacturing, importing, distributing, or leasing a medical device that:
  - Is different from any specification described in the permit or filed report
  - Is entirely or partially unsanitary or made of any substance contaminated by pathogenic microbes or any substance spoiled or decomposed
  - Has caused, or is likely to cause, a hazard to national health and thus against which an order is issued to destroy, suspend use, or revoke the permit
- Repairing, altering, or reengineering a medical device that alters the performance, structure, rating, external appearance, dimensions, or any other element permitted or reported unless the manufacturer or importer alters or rebuilds the device in accordance with specifications stated in the revised permit or filed report
- Using a medical device that fails to obtain approval from MFDS
- Making any indication on an outer package, packing material, or an accompanying document of any appliance other than a medical device to lead any person to misunderstand that the appliance has a function, virtue, or effect similar to that of a medical device; making an advertisement with such misleading contents; or storing or displaying an appliance marked or advertised with such misleading contents with the intent to distribute or lease it

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Compliance with Korean GMP (KGMP) Standards
MFDS requires all device Classes II and above to comply with KGMP quality system standards in order to be marketed in Korea. KGMP standards are based on, but not identical to, ISO 13485 quality system standards. ISO 13485 certificates issued by a notified body in the EU will not be sufficient. To obtain KGMP certification, documents that pertain to all areas of compliance—including design, risk assessment, technical requirements, and any other quality system requirements—will need to be submitted to an MFDS-authorized third party. Once the application is submitted, your manufacturing site will undergo either a paper audit or an onsite inspection/audit by an authorized third party (Class II devices) or both a third party and MFDS (Class III & IV). It is recommended that you hire an experienced consultant to help you through this process. KGMP certification is good for 3 years.

Postmarket Surveillance
Product license holders, which can be the manufacturer and/or importer, are required to collect postmarketing data in several areas, including adverse events, safety alerts and other emerging safety information, recalls, and, for certain higher-risk products, patient records.

Conclusion
The Korean medical device market represents a significant opportunity for medical device companies and will continue to be an opportunity for some time. Today, Korea’s MFDS is trying to focus on not only safety but also on quality and on conforming more closely to international standards. An agent in Korea will help with navigating the current market entry process and will also be up-to-date on MFDS-mandated changes as they occur. There is no substitute for having a professional third party onsite to help get your medical device to market across the entire process.

Resources
