Over view of Medical Device Regulatory Requirement In Korea

Korea Medical Devic

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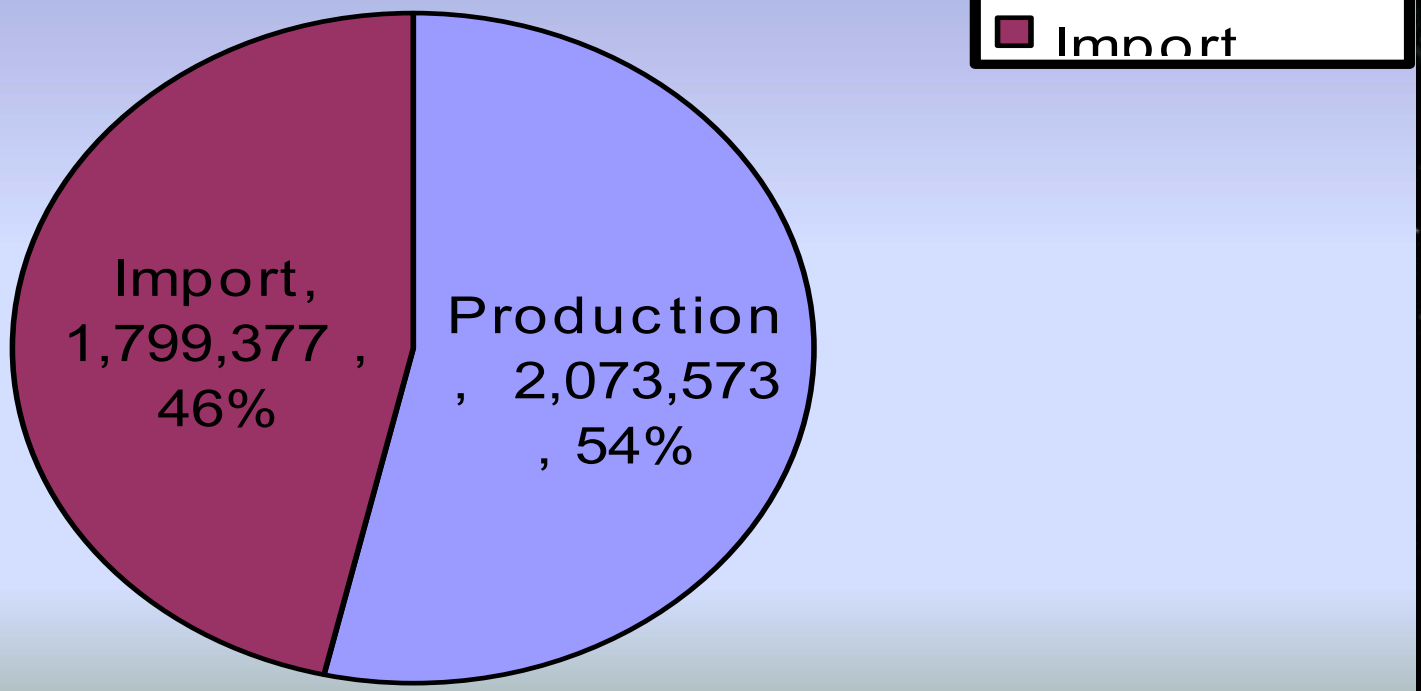
Medical Device Market Status

Function of medical device surveillance Dept.

- Re-examination of new developments devices
- Re-evaluation system
- Tracking devices
- Adverse event reporting and safety alerts
- Market monitor
- Review of Pre-advertisement

Medical Device Market Status

$: 1,000 USD



2006 Production Status

	Item	Production Status	EXPORT	IMPORT
1	Treatment table	65,822	5,772	17,648
2	General medical supplies and apparatus	15,506	5,719	20,315
3	Equipment for medical clinic	31,862	7,996	10,114
4	Anesthesia apparatus	21,215	3,076	16,910
5	Artificial internal organ apparatus	3,933	934	107,055
6	Radiological device	125,611	39,853	208,620
7	Non-ionization diagnostic device	6,306	993	62,812
8	Radiation & laser protective device	1,008	407	198
9	Physical devices for medical use	218,262	113,886	38,737
10	Cardiovascular devices	15,430	9,263	20,882
11	Urological devices	6,119	176	3,898
12	Patient transport	11,676	1,422	18,612
13	Stethoscope	234	115	627

	Item	Production Status	EXPORT	IMPORT
14	Clinical thermometric system	4,315	1,173	4,719
15	Medical in vitro testing apparatus	22,937	18,523	78,355
16	Testing apparatus for Bio-phenomena	373,498	309,463	113,451
17	Speculums for medical use	8,165	4,098	47,080
18	Surgical operation apparatus	87,133	49,539	154,269
19	Electro surgical device	17,729	3,574	30,668
20	Laser apparatus for medical use	44,658	6,609	62,618
21	Needle for syringe and puncture	19,422	8,840	23,577
22	Syringes	60,198	30,591	3,004
23	Infusion instruments	115,832	29,078	118,761
24	Orthopedic devices	41,629	8,224	41,726
25	Dental devices	3,981	1,354	10,405
26	Sight corrective ophthalmic lens	210,916	78,850	68,185
27	Hearing aid	24,912	5	2,564

	Item	Production Status	EXPORT	IMPORT
28	Acupuncture and moxibustion apparatus	7,699	1,708	1,991
29	Magnetic induction apparatus for medical use	4,295	1,028	1,395
30	Medicinal substance-producing equipment	29,569	4,790	1,308
31	Radiographic supplies	-	124	31,248
32	Suture and ligature	19,950	2,642	22,852
33	Orthopedic materials	53,224	20,670	227,608
34	Human tissue and organ substitute	817	21	48,475
35	Splints	22,416	6,356	2,572
36	Test chart for visual acuity and color blindness	2,852	2,529	991
37	Contraceptive device	8,907	17,368	3,779
38	Surgical supplies	18,453	51	32,824
39	Dental Materials	347,082	20,588	138,524
Total		**2,073,573**	**817,409**	**1,799,377**

Medical Device Market Status

- Number of Medical Service Institutions

2004

General Hospital	Hospital	Clinic	Etal hospital & Dentist's office	Herb Doctor's office	Special Hospital	Affiliated Hospital
290	794	25,412	12,520	9,765	102	187

- Number of doctors and nurses

Doctors	Dentists	Herb doctors	Nurses
85,369	21,581	15,271	213,644

Pre-market requirement

The requirements of medical device registration and regulations

Anyone who wants to manufacture or import medical devices for sale should get

- Approval (Class II, III, IV) or
- Submit product notification (Class I)

Pre-market requirement

- Approval (Class II, III, IV)
  - Review of technical file
  - Type test
  - Approval of manufacturing or Importing
  - Quality management system (for sale)

- Notification (Class I)
  - Submit product notification form
  - Approval of manufacturing or Importing
  - Quality management system (for sale)

Medical Device Classification

- Classify into four different categories

  - according to its substantial risks, contacting area and the information of the product's safety and effectiveness, etc.

CLASS	RISK LEVEL	DEVICE EXAMPLES
I	Low Risk	Simple surgical instruments / tongue depressors
II	Low-moderate Risk	Hypodermic Needles / suction implants
III	High-moderate Risk	Lung ventilator / orthopaedic implants
IV	High Risk	Heart valves / implantable defibrillator

The procedure and the review timing of registration

procedure	document	time
Review of Technical file	Technical file Test reports	55 days
Type test	Technical file Test method/criteria	30 ~ 45days
Approval of Manufacture /Import	Certification of manufacture List of facilities	25days 10day
Audit of quality system	Requirements for ISO 13485 Certification ISO 13485	30days

- Medical product registration and testing : KFDA accept testing reports complied GLP, CB scheme
- Clinical trial requirements of medical devices

  - Comply with GCP

  - Choice of clinical hospital :

    Named hospital by KFDA

  - Number of cases, the cost, etc :

    Upon protocol of clinical trial study

- There are requirements on quality system in medical device manufacturers and sales firms

  Based on ISO 13485
- The period of validity of registration certificate : expired period
- The requirements of re-registration : No

PMS and management

- The main function organization of surveillance
  - Tracking
  - Voluntary recall
  - Adverse event/Safety alert reporting
  - Re-examination
  - Re-evaluation

Voluntary recall/A.E/S.A reporting

- Parties required for reporting:
  Manufacturers, Distributors, Repairers, Rental firms
  Hospitals, Veterinary clinics

- Reportable events
  - Voluntary recalls
  - Device-related death or serious adverse events
  - Information on potential adverse events

A.E/S.A reporting

- Timeframe
- Death or life-threatening adverse events
  - Initial report within 7days, Additional follow-up report for detailed information within 8 days
- Events extending the length of hospital stay, disability or reduction of function that cannot be recovered, adverse reactions causing congenital deformity or abnormality : report within 15 days
- Voluntary recall : report within 30 days

A.E/S.A reporting

- Report to the KFDA
  - Regulations for Reporting Adverse Events and Safety Alerts of Medical Devices Form 1
  - Firms must keep such report in file for more than two years

감사합니다

Hee-Byung Park
Executive Director
KMDICA
hebpark@medinet.or.kr