Classifications of medical devices and PMDL revision in Japan

I. Classification of Medical Devices and Approvals

Class	Classification in Japan	Explanation	Examples of Medical Devices	Approval	Manufacturer	MAH*	Retail/Rental
I	General Medical Devices	Those considered to have extremely low risk to the human body even when a failure occurs	Steel instruments, External diagnosis devices, Stethoscope	Notification	Registration	3rd Class MAH	———
II	Controlled Medical Devices	Those considered to have relatively low risk to the human body even when a failure occurs	MRI, Electronic hemopiezometer, Electronic endoscopy, Ultrasonic diagnostic equipment	Third-party certification		2nd Class MAH	Notification
III	Specially Controlled Medical Devices	Those considered to have relatively high risk to the human body when a failure occurs	Dialyzer, Artificial respirator	Third-party certification or Minister's Approval		1st Class MAH	License
IV		Those that are highly invasive to the patient and potentially have a direct impact on human life when a failure occurs	Pace maker, Stent, Artificial heart valve	Minister's Approval			

The differences among "Minister's Approval", "Third-party certification" and "Notification" are followings:
- Minister's Approval : PMDA** investigate the devices and certificate to sell on behalf of MHLW***.
- Third-party certification : Third party institution certificates under the standards of MHLW.
- Notification : Medical devices will be able to deal by notification to PMDA.

In the Specially Controlled Medical Devices, the required approval are different by the kinds of medical devices.

* MAH : Marketing Authorization Holder
** PMDA : The Pharmaceuticals and Medical Devices Agency
*** MHLW : Ministry of Health, Labour and Welfare

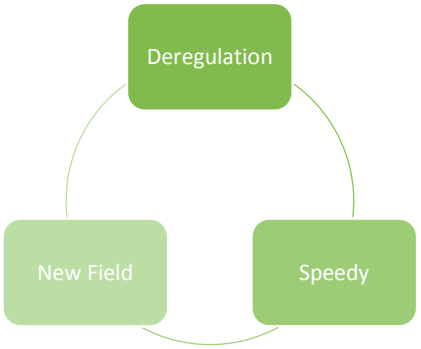
II. Classification of Repair

Class	Specially Designated	Non-specially Designated
1	Imaging diagnosis systems, etc.	
2	Measuring/monitoring systems, etc.	
3	Medical equipment and apparatus for treatment and/or facilities	
4	Artificial organs, etc.	
5	Optical equipment, etc.	
6	Physical therapy devices, etc.	
7	Dental devices, etc.	
8	In-vitro test devices, etc.	
9	Steel instruments, home-care products, etc.	

"Specially designated maintenance management required medical devices" are designated by MHLW which might influence to diagnosis and treatment. To treat those devices, the repair license for specially controlled are required.

III. Three points of PMDL* revision

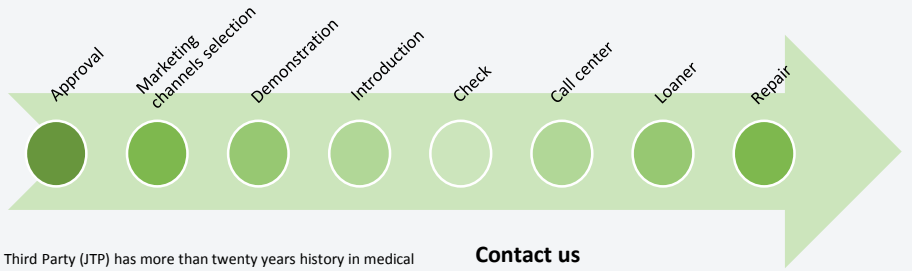
*PMDL: Pharmaceuticals and Medical Devices Law



In 2014, the medical devices regulations has revised to Pharmaceuticals and Medical Devices Law (PMDL) from the Japan's Pharmaceutical Affairs Law (PAL). Since medical devices classification has added to PMDL, the regulation is optimized for medical devices.
Followings are points of revision:

Deregulation	Since classifications of approval are optimized for medical devices, devices which is considered lower risk are able to deal simpler.
Speedy	The coverage of regulation by third-party institution are extended, so the procedure become more speedily.
New Field	Regulations of the new fields such as stand-alone programs or regenerative medical programs which is expected to make new market in Japan are included.

Service package for Pharmaceuticals and Medical Devices Law



Japan Third Party (JTP) has more than twenty years history in medical devices repair/maintenance, call center or sales support. JTP's services with highly experienced quality provides total solution for entering medical devices market in Japan, from the approval process to the post-marketing support.

For more details:
https://www.jtp.co.jp/en/sv/en-life-sciences/medical/sp-pmdl/

Contact us
Japan Third Party Co., Ltd. (JTP)

〒140-0001
14F, Gotenyama-Trust Tower, 4-7-35, Kitashinagawa, Shinagawa-ku, Tokyo, 140-0001, Japan.

Web： https://www.jtp.co.jp/en
Mail ： marketing@jtp.co.jp