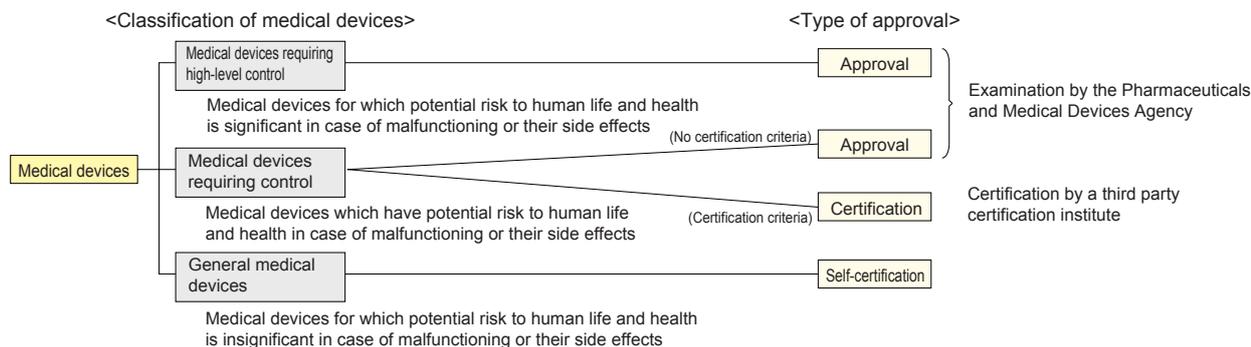


## Approval and Licensing System for Medical Devices

### Overview Classification of Examination for the Approval of Medical Devices



### Detailed Data 1 Number of Approvals for Marketing Medical Devices

(As of the end of 2007)

Classification	Class 1 medical devices	Class 2 medical devices	Class 3 medical devices	Total
Marketing	569	929	1,043	2,541

Source: Pharmaceutical and Food Safety Bureau, MHLW  
 (Note) Licenses are granted by prefecture governors. (Since April 1, 2005)

### Detailed Data 2 Number of Approvals for Manufacturing, Import, and Marketing Medical Devices (2007)

		Medical devices
Manufacturing	Approval	54
	Approval with partial revision	49
	Total	103
Approval	Approval	90
	Approval with partial revision	29
	Total	119
Marketing	Approval	1,601
	Approval with partial revision	353
	Total	1,954

Source: Pharmaceutical and Food Safety Bureau, MHLW

### Detailed Data 3 Number of Approvals for Manufacturing Medical Devices

	Medical devices
Manufacturing	3,877
Repairs	5,713

Source: Pharmaceutical and Food Safety Bureau, MHLW (As of the end of 2007)  
 (Note) Licenses are granted by prefecture governors since April 1997. (Excluding some medical devices)