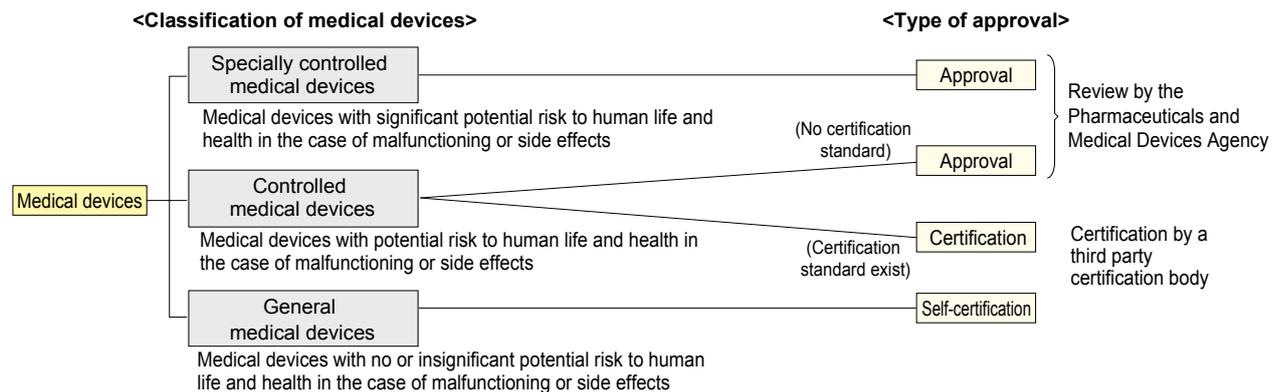


Medical Device Approval/Licensing System

Overview

Review for the Approval of Medical Devices



Detailed Data 1

Number of Licenses for Marketing Authorization Holder

(As of the end of 2010)

Category	Class 1 medical devices	Class 2 medical devices	Class 3 medical devices	Total
Marketing	591	930	938	2,459

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

Detailed Data 2

Number of Approvals for Manufacturing, Import, and Marketing Medical Devices (2010)

		Medical devices
Manufacturing	Approval	0
	Approval with partial change	10
	Total	10
Import	Approval	73
	Approval with partial change	21
	Total	94
Marketing	Approval	705
	Approval with partial change	567
	Total	1,272

Source: Pharmaceutical and Food Safety Bureau, MHLW

Detailed Data 3

Number of Licenses for Manufacturing Medical Devices, etc.

	Medical devices
Manufacturing	3,571
Repairs	6,268

Source: Pharmaceutical and Food Safety Bureau, MHLW (as of the end of 2010)
 (Note) Licenses are granted by prefectural governors from April 1997 (excluding some medical devices).