Overview Classification of Examination for the Approval of Medical Devices

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Medical devices	Medical devices requiring high-level control Medical devices for which potential risk to human life and health is significant in case of malfunctioning or their side effects (No certification)	Approval	Examination by the Pharmaceuticals and Medical Devices Agency
	Medical devices requiring control (Certification and health in case of malfunctioning or their side effects	Cortification	Certification by a third party certification institute
	General medical devices	Self-certification	
	Medical devices for which potential risk to human life and health		

is insignificant in case of malfunctioning or their side effects

Detailed Data 1 Number of Approvals for Marketing Medical Devices

Classification	Class 1 medical devices	Class 2 medical devices	Class 3 medical devices	Total
Marketing	576	919	936	2,431

(As of the end of 2008)

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

Detailed Data 2 Number of Approvals for Manufacturing, Import, and Marketing Medical Devices (2009)

	Medical devices	
	Approval	4
Manufacturing	Approval with partial revision	7
	Total	11
	Approval	11
Approval	Approval with partial revision	6
	Total	17
	Approval	1,363
Marketing	Approval with partial revision	590
	Total	1,953

Source: Pharmaceutical and Food Safety Bureau, MHLW

Detailed Data 3 Number of Approvals for Manufacturing Medical Devices

	Medical devices
Manufacturing	3,613
Repairs	5,952

Source: Pharmaceutical and Food Safety Bureau, MHLW (As of the end of 2009)

(Note) Licenses are granted by prefecturel governors since April 1997. (Excluding some medical devices)