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 2008)

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

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
Manufacturing	Approval	4
	Approval with partial revision	7
	Total	11
Approval	Approval	11
	Approval with partial revision	6
	Total	17
Marketing	Approval	1,363
	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)