

**Table 19 A list of approved items in 2004 (new medical devices)**

	Date of approval	Brand name (name of company)	Approval/ supplemental change	Generic name	Note
1	September 22, 2004	Kawasumi Potassium adsorption filter (Kawasumi Laboratories, Inc.)	Supplemental Change	Other blood collecting and transfusion device (Potassium adsorption filter)	Cation exchange column used for preventing hyperkalemia by adsorbing and eliminating excessive potassium ions in concentrated human erythrocyte fluid provided for transfusion. (Extension of validity period during re-assessment period)
2	January 12, 2005	Particle radiotherapy facilities (carbon ions / proton type) (Mitsubishi Electric Co.)	Supplemental Change	Other particle accelerator for radiotherapy (Particle radiotherapy facilities)	Equipment for particle radiotherapy with high-energy proton or carbon-ion beam accelerated for treating solid tumors and/or brain tumors. (First kind of apparatus in which carbon-ion beams are added as a beam type.) <Priority review>
3	January 24, 2005	Gelpart (Yamanouchi Pharmaceutical Co., Ltd.)	Approval	Other surgical and orthopedics operating supplies (multiporous gelatine particles)	First equipment for arterial embolism used for transcatheter arterial embolization in patients with hepatocellular carcinoma.
4	January 24, 2005	MULTI-LINK PIXEL stent (Guidant Japan K.K.)	Approval	Stent	Stent designed for use in small vessels of less than 2.5mm for which coronary stents were not indicated till now. This stent is limited to the treatment of abrupt or threatened abrupt closure with failed interventional therapy of <i>de novo</i> and restenotic native coronary artery lesions with reference vessel diameter from 2.25 to

					2.5mm (lesion length, less than 25mm).
5	March 2, 2005	RFA system (Boston Scientific Japan K.K.)	Approval	Electrosurgical unit	RF ablation device which coagulates malignant hepatic tumors through the application of heat generated by radio frequency wave. Compared with devices already approved, the maximum output has been increased to 200W and an electrode with a larger expansion diameter (4cm) has been added.
6	March 25, 2005	JMS Dialysis console GC-110N (JMS Co., Ltd.)	Approval	Hemodialysis equipment	A hemodialysis equipment developed for the purpose of safer dialysis therapy, with the first system to have automated control functions for some processes such as priming of blood circuit and dialyzer, blood removal at initiation of dialysis, rapid fluid replacement during dialysis, and return of blood at the end of dialysis.
7	March 25, 2005	ASD closure set (Japan Lifeline Co Ltd.)	Approval	Vascular prosthesis (device for percutaneous atrial septal defect closure)	This is the first medical device for the percutaneous closure of secundum atrial septal defect by placing the main body (septal occluder) at the defect using the delivery system.
8	March 25, 2005	SynchroMed EL pump (Medtronic Japan Co., Ltd.)	Approval	Other infusion apparatus (Implantable pump)	This pump is indicated for intrathecal infusion of baclofen for severe spasticity of spinal or cerebral origin (limited to the patient for whom conventional therapy was not effective). <Orphan medical device>