Surgical Equipment	880.5725	Infusion pump (performance standards)	2
	886.3100	Ophthalmic tantalum clip	2
	886.3300	Absorbable implant (scleral buckling method)	2
	886.4100	Radiofrequency electrosurgical cautery apparatus	2
	886.4115	Thermal cautery unit	2
	886.4150	Vitreous aspiration and cutting instrument	2
	886.4170	Cryophthalmic unit	2
	886.4250	Ophthalmic electrolysis unit (AC-powered device)	1
	886.4335	Operating headlamp (AC-powered device)	1
	886.4390	Ophthalmic laser	2
	886.4392	Nd:YAG laser for posterior capsulotomy	2
	886.4400	Electronic metal locator	1
	886.4440	AC-powered magnet	1
	886.4610	Ocular pressure applicator	2
	886.4690	Ophthalmic photocoagulator	2
	886.4790	Ophthalmic sponge	2
	886.5100	Ophthalmic beta radiation source	2
	none	Ophthalmoscopes, replacement batteries, hand-held	1

Orthopedic Panel

Product Family	Section No	Device Name	Tier
Implants	888.3010	Bone fixation cerclage	2
	888.3020	Intramedullary fixation rod	2
	888.3030	Single/multiple component metallic bone fixation appliances and accessories	2
	888.3040	Smooth or threaded metallic bone fixation fastener	2
	888.3050	Spinal interlaminal fixation orthosis	2
	888.3060	Spinal intervertebral body fixation orthosis	2
Surgical Equipment	888.1240	AC-powered dynamometer	2
	888.4580	Sonic surgical instrument and accessories/attachments	2
	none	Accessories, fixation, spinal interlaminal	2
	none	Accessories, fixation, spinal intervertebral body	2
	none	Monitor, pressure, intracompartmental	1
	none	Orthosis, fixation, spinal intervertebral fusion	2
	none	Orthosis, spinal pedicle fixation	
	none	System, cement removal extraction	1

Physical Medicine Panel

Product Family	Section No	Device Name	Tier
Diagnostic Equipment	890.1225	Chronaximeter	2
	890.1375	Diagnostic electromyograph	2
	890.1385	Diagnostic electromyograph needle electrode	2
	890.1450	Powered reflex hammer	2
	890.1850	Diagnostic muscle stimulator	2
or (Therapy)	890.5850	Powered muscle stimulator	2

Therapeutic Equipment	890.5100	Immersion hydrobath	2
	890.5110	Paraffin bath	2
	890.5500	Infrared lamp	2
	890.5720	Water circulating hot or cold pack	2
	890.5740	Powered heating pad	2

Radiology Panel

Product Family	Section No	Device Name	Tier
MRI	892.1000	Magnetic resonance diagnostic device	2
Ultrasound Diagnostic	884.2660	Fetal ultrasonic monitor and accessories	2
	892.1540	Nonfetal ultrasonic monitor	
	892.1560	Ultrasonic pulsed echo imaging system	2
	892.1570	Diagnostic ultrasonic transducer	2
	892.1550	Ultrasonic pulsed doppler imaging system	
Angiographic	892.1600	Angiographic x-ray system	2
Diagnostic X-Ray	892.1610	Diagnostic x-ray beam-limiting device	2
	892.1620	Cine or spot fluorographic x-ray Camera	2
	892.1630	Electrostatic x-ray imaging system	2
	892.1650	Image-intensified fluoroscopic x-ray system	2
	892.1670	Spot film device	2
	892.1680	Stationary x-ray system	2
	892.1710	Mammographic x-ray system	2
	892.1720	Mobile x-ray system	2
	892.1740	Tomographic x-ray system	1
	892.1820	Pneumoencephalographic chair	2
	892.1850	Radiographic film cassette	1
	892.1860	Radiographic film/cassette changer	1
	892.1870	Radiographic film/cassette changer programmer	2
	892.1900	Automatic radiographic film processor	2
	892.1980	Radiologic table	1

CT Scanner	892.1750	Computed tomography x-ray system	2

Radiation Therapy	892.5050	Medical charged-particle radiation therapy system	2
	892.5300	Medical neutron radiation therapy system	2
	892.5700	Remote controlled radionuclide-applicator system	2
	892.5710	Radiation therapy beam-shaping block	2
	892.5730	Radionuclide brachytherapy source	2
	892.5750	Radionuclide radiation therapy system	2
	892.5770	Powered radiation therapy patient support assembly	2
	892.5840	Radiation therapy simulation system	2
	892.5930	Therapeutic x-ray tube housing assembly	1

Nuclear Medicine	892.1170	Bone densitometer	2
	892.1200	Emission computed tomography system	2
	892.1310	Nuclear tomography system	1
	892.1390	Radionuclide rebreathing system	2

General/Plastic Surgery Panel

Product Family	Section No	Device Name	Tier
Surgical Lamps	878.4630	Ultraviolet lamp for dermatologic disorders	2
	890.5500	Infrared lamp	2
	878.4580	Surgical lamp	2
Electrosurgical Cutting Equipment	878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	2
	878.4400	Electrosurgical cutting and coagulation device and accessories	2
Miscellaneous	878.4780	Powered suction pump	2

APPENDIX 3

AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES	
EC access to the U.S. market	U.S. access to the EC market

• Belgium Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie • Denmark Sundhedsministeriet • Germany Bundesministerium für Gesundheit • Greece Υπουργείο Υγείας Ministry of Health • Spain Ministerio de Sanidad y Consumo • France Ministère de l'emploi et de la solidarité • Ireland Department of Health • Italy Ministero della Sanitá • Luxembourg Ministère de la Santé • Netherlands De Minister van Volksgezondheid, Welzijn en Sport • Austria Bundesministerium für Arbeit, Gesundheit und Soziales • Portugal Ministerio da Saude • Finland Sosiaali-ja terveysministeriö/social-och hälsovårdsministeriet • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • United Kingdom Department of Health	Food and Drug Administration (FDA)

APPENDIX 4

CONFORMITY ASSESSMENT BODIES

EC access to the U.S. market	U.S. access to the EC market
Conformity assessment bodies located in the EC shall be designated by the Authorities identified in Appendix 3. (to be provided by the EC)	Conformity assessment bodies located in the U.S. shall be designated by the Authorities identified in Appendix 3. (to be provided by the U.S.)