

## Food and Drug Administration, HHS

## § 882.3

882.4250 Cryogenic surgical device.  
882.4275 Dowel cutting instrument.  
882.4300 Manual cranial drills, burrs, trephines, and their accessories.  
882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.  
882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.  
882.4325 Cranial drill handpiece (brace).  
882.4360 Electric cranial drill motor.  
882.4370 Pneumatic cranial drill motor.  
882.4400 Radiofrequency lesion generator.  
882.4440 Neurosurgical headrests.  
882.4460 Neurosurgical head holder (skull clamp).  
882.4500 Cranioplasty material forming instrument.  
882.4525 Microsurgical instrument.  
882.4535 Nonpowered neurosurgical instrument.  
882.4545 Shunt system implantation instrument.  
882.4560 Stereotaxic instrument.  
882.4600 Leukotome.  
882.4650 Neurosurgical suture needle.  
882.4700 Cottonoid paddie.  
882.4725 Radiofrequency lesion probe.  
882.4750 Skull punch.  
882.4800 Self-retaining retractor for neurosurgery.  
882.4840 Manual rongeur.  
882.4845 Powered rongeur.  
882.4900 Skullplate screwdriver.

### Subpart F—Neurological Therapeutic Devices

882.5030 Methyl methacrylate for aneurysmorrhaphy.  
882.5050 Biofeedback device.  
882.5070 Bite block.  
882.5150 Intravascular occluding catheter.  
882.5175 Carotid artery clamp.  
882.5200 Aneurysm clip.  
882.5225 Implanted malleable clip.  
882.5235 Aversive conditioning device.  
882.5250 Burr hole cover.  
882.5275 Nerve cuff.  
882.5300 Methyl methacrylate for cranioplasty.  
882.5320 Preformed alterable cranioplasty plate.  
882.5330 Preformed nonalterable cranioplasty plate.  
882.5360 Cranioplasty plate fastener.  
882.5500 Lesion temperature monitor.  
882.5550 Central nervous system fluid shunt and components.  
882.5800 Cranial electrotherapy stimulator.  
882.5810 External functional neuromuscular stimulator.  
882.5820 Implanted cerebellar stimulator.  
882.5830 Implanted diaphragmatic/phrenic nerve stimulator.  
882.5840 Implanted intracerebral/subcortical stimulator for pain relief.

882.5850 Implanted spinal cord stimulator for bladder evacuation.  
882.5860 Implanted neuromuscular stimulator.  
882.5870 Implanted peripheral nerve stimulator for pain relief.  
882.5880 Implanted spinal cord stimulator for pain relief.  
882.5890 Transcutaneous electrical nerve stimulator for pain relief.  
882.5900 Preformed craniostomosis strip.  
882.5910 Dura substitute.  
882.5940 Electroconvulsive therapy device.  
882.5950 Artificial embolization device.  
882.5960 Skull tongs for traction.  
882.5970 Cranial orthosis.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 44 FR 51730-51778, Sept. 4, 1979, unless otherwise noted.

### Subpart A—General Provisions

#### § 882.1 Scope.

(a) This part sets forth the classification of neurological devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a pre-market notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a neurological device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[52 FR 17739, May 11, 1987]

#### § 882.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval