

§ 882.5200

malformations that are difficult to attach directly by reducing the blood pressure and blood flow to the aneurysm or malformation.

(b) *Classification.* Class II (performance standards).

§ 882.5200 Aneurysm clip.

(a) *Identification.* An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.

(b) *Classification.* Class II (performance standards).

§ 882.5225 Implanted malleable clip.

(a) *Identification.* An implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude an intracranial blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tissue or a mechanical device in place in a patient.

(b) *Classification.* Class II (performance standards).

§ 882.5235 Aversive conditioning device.

(a) *Identification.* An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undesirable behavioral characteristics.

(b) *Classification.* Class II (performance standards).

§ 882.5250 Burr hole cover.

(a) *Identification.* A burr hole cover is a plastic or metal device used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.

(b) *Classification.* Class II (performance standards).

§ 882.5275 Nerve cuff.

(a) *Identification.* A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).

(b) *Classification.* Class II (performance standards).

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§ 882.5300 Methyl methacrylate for cranioplasty.

(a) *Identification.* Methyl methacrylate for cranioplasty (skull repair) is a self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.

(b) *Classification.* Class II (performance standards).

§ 882.5320 Preformed alterable cranioplasty plate.

(a) *Identification.* A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

§ 882.5330 Preformed nonalterable cranioplasty plate.

(a) *Identification.* A preformed nonalterable cranioplasty plate is a device that is implanted in a patient to repair a skull defect and is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

§ 882.5360 Cranioplasty plate fastener.

(a) *Identification.* A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium, or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

(b) *Classification.* Class II (performance standards).

§ 882.5500 Lesion temperature monitor.

(a) *Identification.* A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radio-frequency (RF) lesion generator and probe.

(b) *Classification*. Class II (performance standards).

§ 882.5550 Central nervous system fluid shunt and components.

(a) *Identification*. A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

(b) *Classification*. Class II (performance standards).

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification*. A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

(b) *Classification*. Class III (premarket approval).

(c) *Date a PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 60 FR 43969, Aug. 24, 1995; 62 FR 30457, June 4, 1997]

§ 882.5810 External functional neuromuscular stimulator.

(a) *Identification*. An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

(b) *Classification*. Class II (performance standards).

§ 882.5820 Implanted cerebellar stimulator.

(a) *Identification*. An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cere-

bellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification*. Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 26, 1984. Any implanted cerebellar stimulator that was not in commercial distribution before May 28, 1976, or that has not on or before September 26, 1984 been found by FDA to be substantially equivalent to an implanted cerebellar stimulator that was in commercial distribution before May 28, 1976 shall have an approved PMA or declared completed PDP in effect before beginning commercial distribution.

[44 FR 51730-51778, Sept. 4, 1979 and 49 FR 26574, June 28, 1984]

§ 882.5830 Implanted diaphragmatic/phrenic nerve stimulator.

(a) *Identification*. An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification*. Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required*. A PMA or a notice of completion of a PDP is required to be filed