

**§ 882.5235**

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 (special controls), except for electrical stimulation devices for self-injurious or aggressive behavior. Electrical stimulation devices for self-injurious or aggressive behavior are banned. See § 895.105 of this chapter.

[44 FR 51730, Sept. 4, 1979, as amended at 85 FR 13354, Mar. 6, 2020]

**§ 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).

**§ 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).

**21 CFR Ch. I (4–1–25 Edition)**

**§ 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