AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloonlike sacs formed on blood vessels) or other intracranial vascular 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).

§ 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.