§ 882.5175 Carotid artery clamp.

(a) Identification. A carotid artery clamp is a device that is surgically 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).

§ 882.5300 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).