in subpart E of part 807 of this chapter when it is a prescription battery powered device that is indicated for relaxation training and muscle reeducation and prescription use, subject to §882.9.

§ 882.5070 Bite block.

(a) Identification. A bite block is a device inserted into a patient’s mouth to protect the tongue and teeth while the patient is having convulsions.

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

§ 882.5150 Intravascular occluding catheter.

(a) Identification. An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

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

(c) Date PMA or notice of completion of a PDP is required. A PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 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).