Subpart E—Neurological Surgical Devices

§882.4030 Skull plate anvil.

(a) Identification. A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §882.9.


§882.4060 Ventricular cannula.

(a) Identification. A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(b) Classification. Class I (general controls). When made only of surgical grade stainless steel, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9.


§882.4100 Ventricular catheter.

(a) Identification. A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

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

§882.4125 Neurosurgical chair.

(a) Identification. A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §882.9.


§882.4150 Scalp clip.

(a) Identification. A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

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

§882.4175 Aneurysm clip applier.

(a) Identification. An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.

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

§882.4190 Clip forming/cutting instrument.

(a) Identification. A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.


§882.4200 Clip removal instrument.

(a) Identification. A clip removal instrument is a device used to remove surgical clips from the patient.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §882.9.


§882.4215 Clip rack.

(a) Identification. A clip rack is a device used to hold or store surgical clips during surgery.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §882.9.


§882.4250 Cryogenic surgical device.

(a) Identification. A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in