§ 882.4030  
Degree of tremor caused by certain diseases.

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

Subparts C–D [Reserved]

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
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§ 882.4250 Cryogenic surgical device.
(a) Identification. A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.
(b) Classification. Class II (performance standards).

§ 882.4275 Dowel cutting instrument.
(a) Identification. A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.
(b) Classification. Class II (performance standards).

§ 882.4300 Manual cranial drills, burrs, trephines, and their accessories
(a) Identification. Manual cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that are used without a power source on a patient’s skull.
(b) Classification. Class II (performance standards).

§ 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories
(a) Identification. Powered compound cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient’s skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain.
(b) Classification. Class II (performance standards).

§ 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories
(a) Identification. Powered simple cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient’s skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.
(b) Classification. Class II (performance standards).

§ 882.4325 Cranial drill handpiece (brace).
(a) Identification. A cranial drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools that are used on 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.

§ 882.4360 Electric cranial drill motor.
(a) Identification. An electric cranial drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits on a patient’s skull.
(b) Classification. Class II (performance standards).

§ 882.4370 Pneumatic cranial drill motor.
(a) Identification. A pneumatic cranial drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patient’s skull.
(b) Classification. Class II (performance standards).

§ 882.4400 Radiofrequency lesion generator.
(a) Identification. A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.
(b) Classification. Class II (performance standards).

§ 882.4440 Neurosurgical headrests.
(a) Identification. A neurosurgical headrest is a device used to support the patient’s head during a surgical procedure.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in