§ 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 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 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.
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 subpart E of part 807 of this chapter subject to the limitations in §882.9.

§ 882.4460 Neurosurgical head holder (skull clamp).

(a) Identification. A neurosurgical head holder (skull clamp) is a device used to clamp the patient’s skull to hold head and neck in a particular position during surgical procedures.

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

§ 882.4500 Cranioplasty material forming instrument.

(a) Identification. A cranioplasty material forming instrument is a roller used in the preparation and forming of cranioplasty (skull repair) materials.

(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.

§ 882.4525 Microsurgical instrument.

(a) Identification. A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.

(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.

§ 882.4535 Nonpowered neurosurgical instrument.

(a) Identification. A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels,