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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 Neurosurgical head holder (skull clamp).

(a) Identification. A neurosurgical head holder (skull clamp) is a device used to clamp the patient’s skull to

(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 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.

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, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.
(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.


§ 882.4545 Shunt system implantation instrument.
(a) Identification. A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.
(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.


§ 882.4560 Stereotaxic instrument.
(a) Identification. A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient’s brain, spinal cord, or other part of the nervous system.
(b) Classification. Class II (performance standards).

§ 882.4600 Leukotome.
(a) Identification. A leukotome is a device used to cut sections out of the brain.
(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.


§ 882.4650 Neurosurgical suture needle.
(a) Identification. A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.
(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.