§ 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, 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.


§ 882.4560 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
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premarket notification procedures in subpart E of part 807 of this chapter subject to §882.9.

§ 882.4700 Neurosurgical paddle.
(a) A neurosurgical paddle is a pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.
(b) Classification. Class II (performance standards).

§ 882.4725 Radiofrequency lesion probe.
(a) Identification. A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.
(b) Classification. Class II (performance standards).

§ 882.4750 Skull punch.
(a) Identification. A skull punch is a device used to punch holes through a patient’s skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.
(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 §882.9. This exemption does not apply to powered compound cranial drills, burrs, trephines, and their accessories classified under §882.4305.

§ 882.4800 Self-retaining retractor for neurosurgery.
(a) Identification. A self-retaining retractor for neurosurgery is a self-locking device used to hold the edges of a wound open during neurosurgery.
(b) Classification. Class II (performance standards).

§ 882.4840 Manual rongeur.
(a) Identification. A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.
(b) Classification. Class II (performance standards).

§ 882.4845 Powered rongeur.
(a) Identification. A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.
(b) Classification. Class II (performance standards).

§ 882.4900 Skullplate screwdriver.
(a) Identification. A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient’s skull by screws.
(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.

§ 882.5030 Methyl methacrylate for aneurysmorrhaphy.
(a) Identification. Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.
(b) Classification. Class II (performance standards).

§ 882.5050 Biofeedback device.
(a) Identification. A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient’s physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.
(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures...