Food and Drug Administration, HHS

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.


Subpart F—Neurological Therapeutic Devices

§ 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