

§ 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.


§ 882.5150 Intravascular occluding catheter.

(a) Identification. An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

(b) Classification. Class III (premarket approval).