§ 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 §882.9.


§ 882.4700 Neurosurgical paddie.

(a) A neurosurgical paddie 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.