§ 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 § 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 § 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.