

Food and Drug Administration, HHS

§ 882.4535

accessories are bone cutting and drilling instruments used on a patient's skull. The instruments are used with a power source but do not have a clutch mechanism to disengage the tip after penetrating the skull.

(b) *Classification*. Class II (performance standards).

§ 882.4325 Cranial drill handpiece (brace).

(a) *Identification*. A cranial drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools that are used on a patient's skull.

(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.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 61 FR 1123, Jan. 16, 1996; 66 FR 38808, July 25, 2001]

§ 882.4360 Electric cranial drill motor.

(a) *Identification*. An electric cranial drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification*. Class II (performance standards).

§ 882.4370 Pneumatic cranial drill motor.

(a) *Identification*. A pneumatic cranial drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patient's skull.

(b) *Classification*. Class II (performance standards).

§ 882.4400 Radiofrequency lesion generator.

(a) *Identification*. A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

(b) *Classification*. Class II (performance standards).

§ 882.4440 Neurosurgical headrests.

(a) *Identification*. A neurosurgical headrest is a device used to support the

patient's head during a surgical procedure.

(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.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 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.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 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.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 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,