

## Food and Drug Administration, HHS

## § 882.4535

(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, 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.

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