

**§ 882.4125**

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

**§ 882.4125 Neurosurgical chair.**

(a) *Identification*. A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(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]

**§ 882.4150 Scalp clip.**

(a) *Identification*. A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

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

**§ 882.4175 Aneurysm clip applicator.**

(a) *Identification*. An aneurysm clip applicator is a device used by the surgeon for holding and applying intracranial aneurysm clips.

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

**§ 882.4190 Clip forming/cutting instrument.**

(a) *Identification*. A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 59 FR 63012, Dec. 7, 1994]

**§ 882.4200 Clip removal instrument.**

(a) *Identification*. A clip removal instrument is a device used to remove surgical clips from the patient.

(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]

**21 CFR Ch. I (4-1-12 Edition)**

**§ 882.4215 Clip rack.**

(a) *Identification*. A clip rack is a device used to hold or store surgical clips during surgery.

(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 54 FR 25051, June 12, 1989; 59 FR 63012, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

**§ 882.4250 Cryogenic surgical device.**

(a) *Identification*. A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

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

**§ 882.4275 Dowel cutting instrument.**

(a) *Identification*. A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.

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

**§ 882.4300 Manual cranial drills, burrs, trephines, and their accessories**

(a) *Identification*. Manual cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that are used without a power source on a patient's skull.

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

**§ 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.**

(a) *Identification*. Powered compound cranial drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used on a patient's skull. The instruments employ a clutch mechanism to disengage the tip of the instrument after penetrating the skull to prevent plunging of the tip into the brain.

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

**§ 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.**

(a) *Identification*. Powered simple cranial drills, burrs, trephines, and their