

§ 882.4030

degree of tremor caused by certain diseases.

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

Subparts C–D [Reserved]

Subpart E—Neurological Surgical Devices

§ 882.4030 Skull plate anvil.

(a) *Identification*. A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of 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 59 FR 63011, Dec. 7, 1994; 66 FR 38808, July 25, 2001]

§ 882.4060 Ventricular cannula.

(a) *Identification*. A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(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.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 65 FR 2319, Jan. 14, 2000]

§ 882.4100 Ventricular catheter.

(a) *Identification*. A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

(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

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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 applier.

(a) *Identification*. An aneurysm clip applier 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]

§ 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