

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

§ 882.5550 Central nervous system fluid shunt and components.

(a) *Identification*. A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

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

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification*. A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

(b) *Classification*. Class III (premarket approval).

(c) *Date a PMA or notice of completion of a PDP is required*. No effective date has been established of the requirement for premarket approval. See § 882.3.

[44 FR 51730-51778, Sept. 4, 1979, as amended at 52 FR 17740, May 11, 1987; 60 FR 43969, Aug. 24, 1995; 62 FR 30457, June 4, 1997]

§ 882.5810 External functional neuromuscular stimulator.

(a) *Identification*. An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

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

§ 882.5820 Implanted cerebellar stimulator.

(a) *Identification*. An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cere-

bellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification*. Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 26, 1984. Any implanted cerebellar stimulator that was not in commercial distribution before May 28, 1976, or that has not on or before September 26, 1984 been found by FDA to be substantially equivalent to an implanted cerebellar stimulator that was in commercial distribution before May 28, 1976 shall have an approved PMA or declared completed PDP in effect before beginning commercial distribution.

[44 FR 51730-51778, Sept. 4, 1979 and 49 FR 26574, June 28, 1984]

§ 882.5830 Implanted diaphragmatic/phrenic nerve stimulator.

(a) *Identification*. An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification*. Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required*. A PMA or a notice of completion of a PDP is required to be filed