§ 882.5820 Implanted cerebellar stimulator.

(a) Identification. An implanted cerebellar stimulator is a device used to stimulate electrically a patient’s cerebellar 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 a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 26, 1984 for any implanted cerebellar stimulator that was in commercial distribution before May 28, 1976, or that has on or before July 7, 1986 been found to be substantially equivalent to an implanted cerebellar stimulator that was in commercial distribution before May 28, 1976. Any other implanted cerebellar stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in 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 current to subsurface areas of a patient’s brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient’s brain 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 with the Food and Drug Administration on or before March 1, 1989, for any implanted diaphragmatic/phrenic nerve stimulator that was in commercial distribution before May 28, 1976, or that has on or before March 1, 1989, been found to be substantially equivalent to an implanted diaphragmatic/phrenic nerve stimulator that was in commercial distribution before May 28, 1976. Any other implanted diaphragmatic/phrenic nerve stimulator shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[44 FR 51730–51778, Sept. 4, 1979, as amended at 51 FR 12101, Apr. 8, 1986]

§ 882.5840 Implanted intracerebral/subcortical stimulator for pain relief.

(a) Identification. An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient’s brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient’s brain 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 with the Food and Drug Administration on or before March 1, 1989, for any implanted intracerebral/subcortical stimulator for pain relief that was in commercial distribution before May 28, 1976, or that has on or before March 1, 1989, been found to be substantially equivalent to an implanted intracerebral/subcortical stimulator for pain relief that was in commercial distribution before May 28, 1976. Any other implanted intracerebral/subcortical stimulator for pain relief shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.
§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

(a) Identification. An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient’s spinal cord 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 PMA or notice of completion of a PDP is required. A PMA or a notice of completion of a PDP for a device described in paragraph (b) of this section is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any implanted spinal cord stimulator for bladder evacuation that was in commercial distribution before May 28, 1976, or that has, on or before July 13, 1999, been found to be substantially equivalent to an implanted neuromuscular stimulator that was in commercial distribution before May 28, 1976. Any other implanted spinal cord stimulator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

§ 882.5860 Implanted peripheral nerve stimulator for pain relief.

(a) Identification. An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient’s skin to the implanted receiver.

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

§ 882.5870 Implanted peripheral nerve stimulator for pain relief.

(a) Identification. An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient’s skin to the implanted receiver.

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

§ 882.5880 Implanted spinal cord stimulator for pain relief.

(a) Identification. An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient’s spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a patient’s nerve and an external transmitter for transmitting the stimulating pulses across the patient’s skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient’s shoe.