§ 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).

§ 882.5880 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 of the patient’s shoe.

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

(c) Date PMA or notice of completion of PDP is required. A PMA or 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 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.