Food and Drug Administration, HHS

§ 882.5900

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 on 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 II (performance standards).

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) Identification. A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient’s skin to treat pain.

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

§ 882.5900 Preformed craniosynostosis strip.

(a) Identification. A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.