

MAR 17 2000 MAR 20 09:14

Ms. Connie Ficklin
Product Regulation Associate
Medtronic Neurological
800 53rd Avenue NE
Minneapolis, Minnesota 55421-1200

Re: 99P-5298

Dear Ms. Ficklin:

This responds to your citizen petition, dated December 7, 1999, in which Medtronic Neurological requests an exemption from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, as it applies to the device identified as the Medtronic Neurostimulation Model 3861 Temporary Screening Lead. This device is indicated in the management of chronic pain of the trunk and limbs. It is intended to be used temporarily (for a period of no more than 10 days) to screen patients, allowing the physician to evaluate the effectiveness of spinal cord stimulation for pain relief prior to chronic implantation.

The Medtronic Neurostimulation Model 3861 Temporary Screening Lead is designed so that the epidural needle, used to position the lead in the epidural space of the spine, can be easily removed. The lead is threaded through the lumen of the epidural needle. The needle is then removed by sliding it over the proximal end of the lead. For this reason the proximal end of the lead must be small enough to allow the needle to be removed.

Additionally, the proximal end of the lead must be small enough to allow the optional lead anchor to be inserted. The proximal end of the lead is threaded through the lumen of the lead anchor. The lead anchor is then sutured to the surrounding tissue.

The FDA is granting your request. The Medtronic Neurostimulation Model 3861 Temporary Screening Lead that is introduced through the lumen of an epidural needle is exempt from the Performance Standard for Electrode Lead Wires and Patient Cables. Our determination is based on the fact that the intended use of this lead requires, by medical necessity, specific design features for intricate epidural space placement that prevents compliance with the generic requirements of the performance standard for electrode lead wires and patient cables. Where the intended use of a device necessarily requires specific design

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features to accomplish an intricate neurological test safely, the agency may need to rely on alternative requirements and information concerning the design and use of the device. The safety and effectiveness of the Medtronic Neurostimulation Model 3861 Temporary Screening Lead that is introduced through the lumen of an epidural needle remains subject to review by the agency using all other established pre-market and post-market authorities under the Federal Food, Drug and Cosmetic Act.

I trust that this response fully addresses your concerns. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

Drafted:KABerthold:1-24-00
Comment:SECrumpler:2-15-00
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Reviewed:CEUldriks:2-17-00
Init: J Sheehan 3-2-2000
Final:C Uldriks 3-3-2000

cc:
HFA-224
HFA-305 (Docket #99P-5298)
HFR-CE800
HFZ-1
HFZ-3
HFZ-15 (JSheehan, MHanna, Files) ✓
HFZ-300
HFZ-305 (Precedent File)
HFZ-340 (3)
HFZ-341 (Berthold, Firm File)

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