K964172

Medtronic

Medtronic Neurological
800 53rd Avenue NE
P.O. Box 1250
Minneapolis, MN 55440-9087
(612) 572-5000
1-800-328-0810
FAX: (612) 572-5078

June 30, 1997

JUL - 3 1997

RE: 510(k) Notification:
Medtronic Model 3991a, 3992a, 3993a, 3994a Leads

In order to comply with the Safe Medical Devices Act of 1990, these two pages will provide safety and effectiveness information to interested persons.

SUMMARY OF SAFETY AND EFFECTIVENESS

The Medtronic Model 3991a series of Transverse Tripolar™ Leads, or TTL™ leads are indicated for use for SCS for chronic intractable pain of truck or limbs, as for the Model 3982 Symmix®, Model 3883, Model 3586 and Model 3487A leads.

Medtronic considers the Model 3991a series of spinal cord stimulation leads to be substantially equivalent to the current Model 3982 Symmix lead K913993 in paddle size, the Model 3991 series of SCS leads (K952459) in paddle and electrode configuration, the Models 3487A (K923931), 3888 (K910199, K923567), and 3587A (K884948) leads for the lead body design and composition, and other commercially available spinal cord stimulation leads.

There are three modifications in the Model 3991a series of leads from the original Model 3991C (K952459). These modifications are discussed as follows:

A. Spiral-wound wires in lead body.
This change was recommended by Medtronic mechanical engineers as a result of Returned Product Analysis of one explanted lead and bench tests on similar Model 3991C leads. Hence it was done as a result of a single device failure. The new design minimizes forces being applied to the welds between lead body wires and connector rings in the proximal end of the lead, which was the site of the failure of the single returned lead.

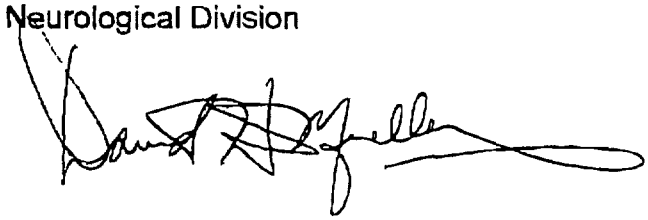
B. Crimps and ferrules in the paddle.
This change was recommended by Medtronic mechanical engineers as the best way to have the spiral-wound wires of the lead body connect to the most lateral (edge) contacts of the paddle. Hence it was done to allow the modification a. (above) to be used.

C. ***Radiopaque markers in the tips of the paddle.***
This change was recommended by physicians so that they could best determine the orientation of the paddle relative to vertebral bones using fluoroscopy. Since the electrodes are all located in a relatively small area (10 mm x 10 mm), this helps to align certain contacts, E0, E1 and E2, transversely to the spinal cord.

Therefore, the Model 3991a TTL leads family with alternate design are substantially equivalent to current Medtronic spinal cord stimulation leads.

Sincerely,

MEDTRONIC, INC.
Neurological Division



David H. Mueller
Regulatory Affairs Manager
NeuroStimulation Business

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 1997

Mr. David H. Mueller
Regulatory Affairs Manager
NeuroStimulation Business
Medtronic Neurological
800 53rd Avenue NE
P.O. Box 1250
Minneapolis, Minnesota 55440-9087

Re: K964172
Trade Name: Medtronic TTL® Leads (Models 3991A, 3992A, 3993A, and 3994A)
Regulatory Class: II
Product Code: 84GZB
Dated: April 3, 1997
Received: April 4, 1997

Dear Mr. Mueller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Medtronic Model 3991A Lead Series

Indications For Use Statement

Model 3991A Series Leads are indicated for use for epidural spinal cord stimulation (SCS) as an aid in the treatment of chronic intractable pain of the trunk and/ or limbs.

All other uses are considered investigational.

Prescription Use ✔
(Per 21 CFR 801.109)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964172