Medtronic

Medtronic Neurological
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(612) 572-5000
1-800-328-0810
FAX: (612) 572-5078

K971756

FEB - 3 1998

# SUMMARY OF SAFETY AND EFFECTIVENESS

## I. SUBMITTER

| | |
|---|---|
| *Name and Address:* | Medtronic, Inc.<br>800 53rd Avenue N.E.<br>Minneapolis, MN 55421 |
| *Contact Person:* | Lisa L. Pritchard |
| *Date of Summary Preparation:* | August 29, 1997 |
| *Establishment Registration Number:* | 2182207 |

## II. DEVICE NAME

| | |
|---|---|
| *Device Common or Usual Name:* | Lead for Implanted Spinal Cord Stimulation |
| *Device Trade Name:* | Medtronic® Specify™ Model 3998 Lead |
| *Device Classification Name:* | Implanted Spinal Cord Stimulator for Pain Relief (21 CFR 882.5880) |

## III. PREDICATE DEVICE

Leads for Implanted Spinal Cord Stimulators for Pain Relief:

- Medtronic® Model 3586 Resume® Lead
- Medtronic® Model 3587A Resume II® Lead
- Medtronic® Model 3982 SymMix® Lead
- Medtronic® Model 3983 Lead
- Medtronic® Model 3993 TTL Lead
- Medtronic® Model 3483S Pisces-Sigma® Lead

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## IV. DEVICE DESCRIPTION

The Medtronic Specify Model 3998 Lead is an implantable, permanent lead. It is used to deliver electrical pulses to the dorsal aspect of the spinal cord.

The lead consists of two polyurethane lead bodies joined to one silicone rubber paddle. The lead has two parallel rows of four platinum iridium electrodes on the distal end.

At the proximal end of each lead body are the lead contacts, which fit into a Medtronic in-line, four-conductor connector. The Model 3998 lead can be used with any Medtronic products that have two in-line connectors, including:

- The Mattrix system, Model 3272 receiver
- The Bifurcated Y-extension, Model 7498, which can be used with the Itrel or Xtrel system.

## V. INDICATION FOR USE

The Medtronic® Model 3998 Specify™ Lead is indicated in the management of chronic pain of the trunk and limbs, either as a sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach to chronic pain alleviation.

## VI. COMPARISON TO PREDICATE DEVICES

The Medtronic Specify Model 3998 Lead is substantially equivalent to other Medtronic Spinal Cord Stimulation leads currently in commercial distribution.

a. Product Labeling

Product labeling for each of the Medtronic Spinal Cord Stimulation Leads is substantially equivalent to the proposed product labeling for the Specify Model 3998 lead.

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b. Intended Use

The Medtronic Specify Model 3998 Lead has the same intended use as many of the current Medtronic Spinal Cord Stimulation Leads. The Medtronic Specify Model 3998 Lead is indicated in the management of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach to chronic pain alleviation.

c. Physical Characteristics

In the existing Medtronic Spinal Cord Stimulation leads, and the Specify Model 3998 Lead, the lead consists of two lead bodies attached to a paddle containing eight stimulating electrodes. Electrically and functionally, the Model 3998 Lead is the same as two of Medtronic's current leads combined within one paddle. Medtronic, Inc., supplied an equivalence table comparing the similarities and differences within this physical structure. Materials used are identical to predicate device leads.

d. Anatomical Sites

In the existing Medtronic Spinal Cord Stimulation leads, and the Specify Model 3998 Lead, the lead is placed within an epidural space of the spinal cord.

e. Performance Testing

Medtronic, Inc., has provided descriptive data on the test plan and test results for the Specify Model 3998 Lead. These data support that the function and characteristics of the device are suitable for its intended use.

Paddle flex testing was performed which indicated the Model 3998 Specify lead to equal the flex characteristics of other currently available Medtronic leads.

Tensile strength testing was performed to evaluate the separation strength of the lead. This testing indicated the lead to have adequate strength to perform its intended use.

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DC Resistance testing was performed to evaluate the electrode impedance. This testing indicated adequate connections exist.

Additionally, cross circuit impedance testing was performed to evaluate the effectiveness of circuit isolation. This testing concluded isolation to be adequate.

In summary, Medtronic, Inc. has provided information within the 510(k) Premarket Notification to indicate that the Specify™ Model 3998 Lead is safe and effective for its intended use in the treatment of chronic intractable pain of the trunk and limbs. Additionally, the Specify Model 3998 Lead has been shown to be comparable in terms of intended use and technological characteristics to the Spinal Cord Stimulation Leads currently in commercial distribution. The data and information provided within this 510(k) premarket notification adequately support that the Specify Model 3998 Lead is substantially equivalent to other Medtronic Spinal Cord Stimulation Leads currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 3 1998

Ms. Lisa L. Pritchard
Senior Product Regulation Manager
Medtronic, Incorporated
800 53rd Avenue, NE
P.O. Box 1250
Minneapolis, Minnesota 55440-9087

Re: K971756
Trade Name: Medtronic Specify Model 3998 Lead
Regulatory Class: II
Product Code: GZB
Dated: December 10, 1997
Received: December 11, 1997

Dear Ms. Pritchard:

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.

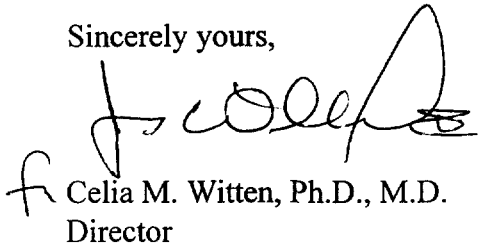
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , 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) 594-4659. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known) K971756

Device Name: Specify™ Model 3998 Spinal Cord Stimulation Lead

Indications for Use:

The Medtronic® Model 3998 Specify™ Lead is indicated in the management of chronic pain of the trunk and limbs, either as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach to chronic pain alleviation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971756

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)