2/9/99

K990104

Medtronic

Medtronic Neurological
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Minneapolis, MN 55421-1200
Internet: www.medtronic.com
Telephone: (612) 514-5000
Toll-free: 1-800-328-0810
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510(k) SUMMARY

I. SUBMITTER

Name and Address:	Medtronic, Inc. Neurological Division 800 53rd Avenue NE Minneapolis, MN 55421
Contact Person:	Lisa L. Pritchard
Date of Summary Preparation:	January 11, 1999
Establishment Registration Number:	2182207

II. DEVICE NAME

Device Common or Usual Name:	Extension for Spinal Cord and Peripheral Nerve Stimulators
Device Trade Name:	Medtronic Model 7495 Extension Kit

III. PREDICATE DEVICE

Extensions for Implanted spinal Cord Stimulation (SCS) and/or Peripheral Nerve Stimulation (PNS) for the treatment of chronic intractable pain.

IV. DEVICE DESCRIPTION

The Medtronic Model 7495 extension kit is used with spinal cord and peripheral nerve stimulation systems to connect stimulation leads to the implanted receiver of externally powered (RF) systems. The extension provides an electrical path to allow stimulation to be delivered to the target site.

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V. INDICATION FOR USE

The Model 7495 extension kit with revised accessories has the same intended use as the current Model 7495 extension kit. These extensions are intended to be surgically implanted as part of a neurostimulation system to treat chronic, intractable pain.

VI. COMPARISON TO PREDICATE DEVICE

The Medtronic Model 7495 extension kit with revised accessories is substantially equivalent to the Medtronic Model 7495 extension kit that is currently in commercial distribution.

a. Intended Use

These extensions are intended to be surgically implanted as part of a neurostimulation system to treat chronic, intractable pain.

b. Principles of Operation

The design and principle of operation of the extension in the revised kit is identical to the currently available Model 7495 extension. The extension provides an electrical path between the neurostimulator and the lead to allow stimulation to be delivered to the target site.

c. Device Performance

Performance of the Model 7495 extension is not affected by the modifications in accessories provided with the extension kit. The design of the extension remains unchanged. Design of the large wedge tip and dual carrier tip tunneling accessories also remains unchanged (these accessories are currently packaged with the Model 7498 extension kit). Changes to the connector boots to add Roman Numeral identification and radiopaque material do not change the performance or use of the connector boot.

d. Bench Testing

Because there is no significant change to the design of the accessory components, mechanical testing is not applicable. The material added to the connector boot has undergone extensive biocompatibility testing and has been determined to be biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Ms. Lisa L. Pritchard
Principal Product Regulation Manager
Medtronic Neurological
800 53rd Avenue NE
Minneapolis, Minnesota 55440-9087

Re: K990104
Trade Name: Medtronic Model 7495 Extension Kit
Regulatory Class: II
Product Codes: GZB and GZF
Dated: January 11, 1999
Received: January 12, 1999

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 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) 594-4659. 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

APPENDIX 2

INDICATIONS FOR USE STATEMENT

510(k) Number (if Known):_____

Device Name: Model 7495 Extension Kit

Indications For Use:

The Medtronic Model 7495 Extension Kit is intended for use with implanted spinal cord or peripheral nerve stimulation systems for the treatment of chronic, intractable pain.

(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 K990104

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