K032561

SEP 11 2003

510(k) Summary
Medtronic In-Line Surgical Leads for Neurostimulation
(as required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	Medtronic Neurological
Address:	710 Medtronic Parkway NE Minneapolis, Minnesota 55432.5604 U.S.A.
Telephone Number:	763.505.1465
Contact Person:	Lucy Tan
Date Submission Prepared:	August 19, 2003

B. Device Information

Device Trade Name:	In-Line Surgical Leads for Neurostimulation
Common or usual Name:	Spinal Cord Stimulation Lead Peripheral Nerve Stimulation Lead
Classification Name:	Spinal Cord Stimulators (21 CFR Part 882.5880) Peripheral Nerve Stimulators (21 CFR Part 882.5870)
Classification Code:	GZB – Spinal Cord Stimulators GZF – Peripheral Nerve Stimulators
Predicate Device:	Resume II 3587A – K904507 Resume TL 3986 – K904507 SymMix 3982 - K913993 On-Point – K920567
Device Description:	Quadripolar implantable neurostimulation surgical leads with in-line connector.
Indications for Use:	***Resume II Model 3587A and Resume TL Model 3986A*** are indicated for Spinal Cord Stimulation and Peripheral Nerve Stimulation to aid in the management of chronic intractable pain of the trunk and/or limbs. The peripheral nerve stimulators are used to stimulate electrically a peripheral nerve in patients to relieve severe intractable pain. ***On-Point Model 3987A*** is indicated for Peripheral Nerve Stimulation to aid in the management of

chronic intractable pain of the trunk and/or limbs. The peripheral nerve stimulators are used to stimulate electrically a peripheral nerve in patients to relieve severe intractable pain.

SymMix Model 3982A is indicated for Spinal Cord Stimulation to aid in the management of chronic intractable pain of the trunk and/or limbs.

C. Comparison of Required Technological Characteristics

The technological characteristics of the proposed ILS leads for neurostimulation are substantially equivalent to the noted predicate devices.

D. Performance Data

Performance data that supports the safety and effectiveness of the use of the ILS leads for neurostimulation are included in this 510(k) premarket notification.

E. Conclusion

Medtronic neurostimulation ILS leads (Resume II 3587A, Resume TL 3986A, SymMix 3982A, and On-Point 3987A) are substantially equivalent to the noted predicate devices based on the similarities of technological characteristics, the identical indications for use and the results of the testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2003

Lucy Tan, RAC
Senior Regulatory Affairs Specialist
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, Minnesota 55432

Re: K032561

Trade/Device Name: Resume II Model 3587A
Regulation Number: 21 CFR 882.5880 and 21 CFR 882.5870
Regulation Name: Implanted spinal cord stimulator for pain relief and Implanted peripheral nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZB and GZF

Trade/Device Name: Resume TL Model 3986A
Regulation Number: 21 CFR 882.5880 and 21 CFR 882.5870
Regulation Name: Implanted spinal cord stimulator for pain relief and Implanted peripheral nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZB and GZF

Trade/Device Name: On-Point Model 3987A
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted peripheral nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZF

Trade/Device Name: SymMix Model 3982A
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted spinal cord stimulator for pain relief
Regulatory Class: Class II
Product Code: GZB

Dated: August 19, 2003
Received: August 20, 2003

Dear Ms. Tan:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). You may, therefore, market the devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K032561

Device Name: Resume II In-Line Surgical Lead
Resume TL In-Line Surgical Lead
SymMix In-Line Surgical Lead
On-Point In-Line Surgical Lead

Indications for Use:

Resume II Model 3587A and Resume TL Model 3986A are indicated for Spinal Cord Stimulation to aid in the management of chronic intractable pain of the trunk and/or limbs. They are also indicated for Peripheral Nerve Stimulation. The peripheral nerve stimulators are used to stimulate electrically a peripheral nerve in patients to relieve severe intractable pain.

On-Point Model 3987A is indicated for Peripheral Nerve Stimulation. The peripheral nerve stimulators are used to stimulate electrically a peripheral nerve in patients to relieve severe intractable pain.

SymMix Model 3982A is indicated for Spinal Cord Stimulation to aid in the management of chronic intractable pain of the trunk and/or limbs.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032561