MAR 2 5 2004

K040568 1 of 3

510(k) Summary
Medtronic Neurostimulation Leads
(as required by 21 CFR 807.92)

A. Submitter information

Submitter's Name:	Medtronic Neurological
Address:	710 Medtronic Parkway NE Minneapolis, Minnesota 55432-5604 USA
Telephone Number	763.505.0204
Contact Person:	Doug Atkins
Date Submission Prepared:	February 27, 2004

B. Device Information

Device Trade Name:	**Pisces Z Quad®** lead kit for Spinal Cord Stimulation (SCS) **Pisces Z Quad Compact™** lead kit for Spinal Cord Stimulation (SCS) **Pisces Z Quad Plus®** lead kit for Spinal Cord Stimulation (SCS) **Pisces Quad®** lead kit for Spinal Cord Stimulation (SCS) **Pisces Quad® Compact** lead kit for Spinal Cord Stimulation (SCS) **Pisces Quad® Plus** lead kit for Spinal Cord Stimulation (SCS) **Pisces Octad®** lead kit for Spinal Cord Stimulation (SCS) **Specify™** lead kit for Spinal Cord Stimulation (SCS) **Resume II®** lead kit for Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) **Resume® TL** lead kit for Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) **SymMix®** lead kit for Spinal Cord Stimulation (SCS) **On-Point®** lead kit for Peripheral Nerve Stimulation (PNS) **Verify®** lead kit for Spinal Cord Stimulation (SCS) **Temporary Screening Lead** for Spinal Cord Stimulation (SCS)
Common or Usual Name:	Spinal Cord Stimulation Lead Peripheral Nerve Stimulation Lead
Classification Name:	Implanted spinal cord stimulator for pain relief (21 CFR 882.5880) Implanted peripheral nerve stimulator for pain relief (21 CFR 882.5870)

K040568
2003

Classification Code:	GZB—Spinal Cord Stimulators GZF—Peripheral Nerve Stimulators
Predicate Device:	Pisces Quad 3487A—K923931 Pisces Quad Compact 3887—K923931 Pisces Quad Plus 3888—K923567 Pisces Z Quad 3890—K033016 Pisces Z Quad Compact 3891—K033016 Pisces Z Quad Plus 3892—K033016 Specify 3998—K971756 Pisces Octad 3898—K934065 Resume II 3587A—K032561 SymMix 3982A—K032561 Resume TL 3986A—K032561 On-Point 3987A—K032561 Temporary Screening Lead 3861—K912764 Verify 3862—K932202
Device Description:	Resume II 3587A, Resume TL 3986A, On-Point 3987A, and SymMix 3982A are quadripolar implantable neurostimulation surgical leads with in-line connector. Pisces Quad 3487A, Pisces Quad Compact 3887, and Pisces Quad Plus 3888 are percutaneous quadripolar implantable neurostimulation leads. Pisces Z Quad 3890, Pisces Z Quad Compact 3891, and Pisces Z Quad Plus 3892 are low impedance percutaneous quadripolar implantable neurostimulation leads. Pisces Octad 3898 is a percutaneous octapolar implantable neurostimulation lead. Temporary screening lead 3861 is a percutaneous bipolar implantable neurostimulation lead to be used for no more than 10 days. Verify 3862 is a percutaneous quadripolar implantable neurostimulation lead to be used for no more than 10 days. Specify 3998 is an octapolar implantable neurostimulation surgical lead.
Indications for Use:	***Pisces Quad Model 3487A, Pisces Quad Compact Model 3887, Pisces Quad Plus Model 3888, Pisces Z Quad Model 3890, Pisces Z Quad Compact Model 3891, Pisces Z Quad Plus Model 3892, Specify Model 3998, Pisces Octad Model 3898, SymMix Model 3982A, Temporary Screening Lead Model 3861, and Verify Model 3862*** are indicated for Spinal Cord Stimulation to aid in the management of chronic intractable pain of the trunk and/or limbs.

K040568
3 of 3

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.

C. Comparison of Required Technological Characteristics

The technological characteristics of the modified 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 modified neurostimulation leads are included n this 510(k) premarket notification.

E. Conclusion

Medtronic neurostimulation leads (Pisces Quad 3487A, Pisces Quad Compact 3887, Pisces Quad Plus 3888, Pisces Z Quad 3890, Pisces Z Quad Compact 3891, Pisces Z Quad Plus 3892, Specify 3998, Pisces Octad 3898, SymMix 3982A, Temporary Screening Lead 3861, Verify 3862, Resume II 3587A, Resume TL 3986A, 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

MAR 2 5 2004

Doug Atkins
Regulatory Affairs Specialist
710 Medtronic Parkway NE
Minneapolis, Minnesota 55432-5604

Re: K040568

Trade/Device Name: Pisces Z Quad®, Pisces Z Quad Compact™, Pisces Z Quad Plus®, Pisces Quad®, Pisces Quad® Compact, Pisces Quad® Plus, Pisces Octad®, Specify™, Resume® II, Resume® TL, SymMix®, Verify® and Temporary Screening Lead
Regulation Number: 21 CFR 882.5880
Regulation Name: Implanted Spinal Cord Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZB

Trade/Device Name: Resume® II, Resume® TL and On-Point®
Regulation Number: 21 CFR 882.5870
Regulation Name: Implanted Peripheral Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZF

Dated: March 3, 2004
Received: March 5, 2004

Dear Mr. Atkins:

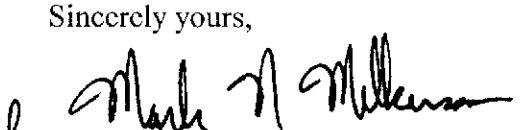
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device 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 device complies 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 device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

510(k) Number (if known): _____

Device Name: Pisces Z Quad® lead
Pisces Z Quad Compact™ lead
Pisces Z Quad Plus® lead
Pisces Quad® lead
Pisces Quad® Compact lead
Pisces Quad® Plus lead
Pisces Octad® lead
Specify™ lead
Resume II® lead
Resume® TL lead
SymMix® lead
On-Point® lead

Indications for Use:

Pisces Quad Model 3487A, Pisces Quad Compact Model 3887, Pisces Quad Plus Model 3888, Pisces Z Quad Model 3890, Pisces Z Quad Compact Model 3891, Pisces Z Quad Plus Model 3892, Specify Model 3998, Pisces Octad Model 3898, SymMix Model 3982A, Temporary Screening Lead Model 3861, and Verify Model 3862 are indicated for Spinal Cord Stimulation to aid in the management of chronic intractable pain of the trunk and/or limbs.

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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040568