DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Mr. David H. Mueller
Regulatory Affairs Manager
NeuroStimulation Business
Medtronic, Inc.
800 53rd Avenue NE
Minneapolis, Minnesota 55421-1200

Re: K011584
Trade/Device Names: Medtronic Spinal Cord and Peripheral Nerve Stimulation Systems for Pain Relief (see enclosed list)
Regulation Numbers: 21 CFR 882.5880 and 21 CFR 882.5870
Regulatory Class: II
Product Codes: GZB and GZF
Dated: May 22, 2001
Received: May 23, 2001

Dear Mr. Mueller:

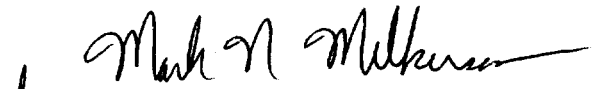
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 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 devices 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 devices as described in your 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 devices 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 devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,



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

Enclosures

FDA REQUIRED INDICATIONS PAGE

510(k) Number: K011584
Device Name(s): Medtronic Spinal Cord Stimulation Systems for Pain Relief and Medtronic Peripheral Nerve Stimulation Systems for Pain Relief

Indications for Use:

The Medtronic X-trel® and Mattrix® Neurostimulation systems are indicated as an aid in the management of chronic, intractable pain of the trunk or limbs. X-trel and Mattrix Receiver Model 3272 systems are also indicated for peripheral nerve stimulation.

Peripheral nerve stimulators are used to stimulate electrically a peripheral nerve in patients to relieve severe intractable pain.

(Please do not write below this line-continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

510(k) Number K011584

(Option Format 3-10-98)