



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 10 1998

Mr. David H. Mueller  
Regulatory Affairs Manager  
Medtronic, Inc.  
Neurological Division  
800 53<sup>rd</sup> Avenue, N.E.  
Minneapolis, Minnesota 55421

Re: K982902

Trade Names: Model 3425 X-trel Transmitter, Model 3465  
RF Receiver/Extension, Model 3586 Lead, Model 3625  
Screener, Model 3470 X-trel Receiver, Model 7495  
Extension, Model 7496 Extension, Model 3587A Lead,  
Models 3987/3988 On-Point Lead, Model 3080 Lead, Model  
3990 Half-Cuff Lead, Model 3272 Mattrix Receiver, Model  
3210 Mattrix Transmitter, Model 3627 Screener, 100%  
Ethylene Oxide Sterilization, Model 3650 Adapter, Model  
3628 Screener, Models 3273/3274 RF Receiver, and Models  
3629/3630 Screener

Regulatory Class: II

Product Code: GZF

Dated: August 13, 1998

Received: August 14, 1988

Dear Mr. Mueller:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) 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 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.

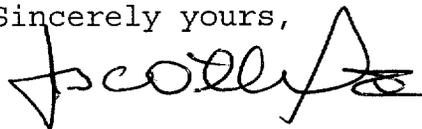
If your devices are classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

Enclosures

510(k) Number (if known) K982902

Device Name: Peripheral Nerve Stimulator for Pain - Multiple Devices

Indications for Use:

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

In order to maintain consistency between products, this indication will be used for all Medtronic PNS indicated devices.

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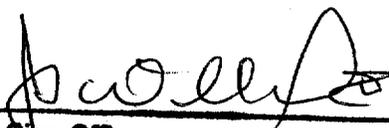
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1/2/96)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K982902