K972043

Medtronic

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AUG 22 1997

May 30, 1997

RE: **510(k) Notification:** Medtronic Model 3273/3274 RF Receiver and Model 3629/3630 Screener

In order to comply with the Safe Medical Devices Act of 1990, these two pages will provide safety and effectiveness information to interested persons.

SUMMARY OF SAFETY AND EFFECTIVENESS

Summary Information

Using a commercially available Medtronic Spinal Cord Stimulation Radiofrequency (RF) Transmitter to provide the appropriate RF signal, the Model 3273/3274 Receiver, when connected to a commercially available Medtronic quadrapolar lead, will provide an electrical signal to three (3) of the four electrodes (with no signal, or "open", supplied to the fourth electrode). The Model 3273/3274 Receiver, when connected to a commercially available Medtronic quadrapolar lead, will have the ability to reduce the stimulation (voltage) of one of two electrode anodes (related to the cathode), ranging from the programmed stimulation parameter of the other anode to zero. This will allow the physician and patient to customize or balance the stimulation to optimally control pain.

The Model 3272/3274 Receiver is substantially equivalent to the Model 3271/3272 Receiver (K934065), Model 3470 Receiver (K904409A), the Model 3462B RF Receiver (K823130), and other commercially available RF receivers.

The Model 3629/3630 Screener is connected to the (temporary) percutaneous extension of a commercially available lead and to a commercially available Medtronic Model 3210 Transmitter for the screening period. This is the same procedure used with commercially available Medtronic Model 3627 Screener. The Model 3629/3630 Screener is basically a "receiver in a box" (the same circuitry of the Model 3273/3274 Receiver is used), so that the stimulation parameters and characteristics of the Model 3273/3274 Receiver are replicated by the screener.

The Model 3273 or 3274 receiver is implanted subcutaneously, and connected to a quadrapolar stimulation lead. Sufficient samples were built and tested with electrical and functional tests to assure that they will receive signals transmitted from a Model 3210 transmitter and antenna, and perform satisfactorily in this environment by delivering electrical pulses to the lead.

The Model 3629 or 3630 screener is outside the patient, and used for a period of days to deliver pulses from a Model 3210 transmitter to percutaneous wires of a quadrapolar lead. Sufficient samples were built and tested with electrical and functional tests to assure that they will perform satisfactorily in this environment.

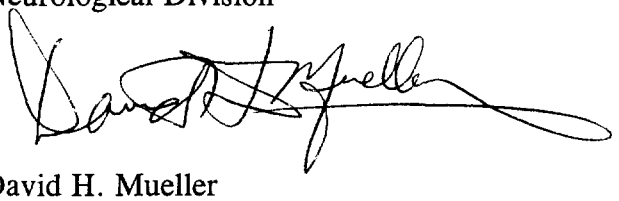
Mechanical, physical and environmental characteristics of these components were not tested, because they should be identical to those of commercially available predicate devices.

The Model 3629/3630 Screener is substantially equivalent to the Model 3625 Screener (K903690B), Model 3627 Screener (K934065), and other commercially available screeners.

Therefore, these devices are substantially equivalent to current Medtronic spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS) systems.

Sincerely,

MEDTRONIC, INC.
Neurological Division



David H. Mueller
Regulatory Affairs Manager
Neurostimulation Business

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 22 1997

Mr. David H. Mueller
Regulatory Affairs Manager
Neurostimulation Business
Medtronic Neurological
800 53rd Avenue NE
Minneapolis, Minnesota 55440

Re: K972043
Trade Name: Model 3273/3274 Receiver and Model 3629/3630 Screener
Regulatory Class: II (two)
Product Code: 84GZB & 84GZF
Dated: May 30, 1997
Received: June 2, 1997

Dear Mr. Mueller:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): __K972043_____

Device Name: __Model 3273/3274 Receiver and Model 3629/3630 Screener___

Indications For Use: Model 3273/3274 Receiver and Model 3629/3630 Screener indicated for use for epidural spinal cord stimulation (SCS) and peripheral nerve stimulation (PNS), as an aid in the treatment 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)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number _____K972043_____

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