Medtronic

FEB - 6 1998

Medtronic Neurological
800 53rd Avenue NE
P.O. Box 1250
Minneapolis, MN 55440-9087
(612) 572-5000
1-800-328-0810
FAX: (612) 572-5078

K972906

SUMMARY OF SAFETY AND EFFECTIVENESS

I. SUBMITTER

Name and Address;	Medtronic, Inc. 830 53rd Avenue N.E. Minneapolis, MN 55421
Contact Person:	Lisa L. Pritchard
Date of Summary Preparation:	October 8, 1997
Establishment Registration Number:	2182207

II. DEVICE NAME

Device Common or Usual Name:	Lead Accessory (Anchor) for Implanted Spinal Cord Stimulation
Device Trade Name	Medtronic Twist Lock Anchor
Device Classification Name:	Implanted Spinal Cord Stimulator for Pain Relief (21 CFR 882.5880)

III. PREDICATE DEVICE

Medtronic Lead Anchor Accessory Model 3550-01

IV. DEVICE DESCRIPTION

The Medtronic Twist Lock Anchor is an implantable device. It is used with Spinal Cord Stimulation (SCS) systems for the treatment of chronic intractable pain of the trunk or limbs.

The anchor is assembled from three parts: the driver and the shell which are made of polysulfone, and a stainless steel pin which is press fitted into the shell. The compression created by the fit of the driver within the shell grips the lead body outer jacket.

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The Medtronic Twist Lock Anchor can be used only with coiled conductor Medtronic Neurological Spinal Cord Stimulation leads that require anchor sleeve and that have an outside diameter of 1.27 mm.

V. INDICATIONS FOR USE

The Medtronic Twist Lock Anchor is indicated as an alternate anchor accessory for use with Spinal Cord Stimulation (SCS) Systems for the treatment of chronic intractable pain of the trunk or limbs. The Twist Lock Anchor can be used only with coiled conductor Medtronic Neurological Spinal Cord Stimulation leads with an outside diameter of 1.27 mm. All other uses are contraindicated.

VI. COMPARISON TO PREDICATE DEVICES

a. Function and Intended Use

The Medtronic Twist Lock Anchor has the same function and intended use as the current silicone rubber anchor. The Medtronic Twist Lock Anchor and the current silicone rubber anchor are indicated for use as alternate spinal cord stimulation lead accessories for use in the treatment of chronic intractable pain of the trunk or limbs. Both are used with spinal cord stimulation leads with an outer diameter of 1.27 mm.

b. Gripping Method and Strength

Both the current silicone rubber anchor and the Twist Lock Anchor grip using compression. The gripping strength of the current silicone rubber anchor and the Twist Lock Anchor are substantially equivalent.

c. Recommended Anatomical Placement and Anchoring Site

Both the current silicone rubber anchor and the Medtronic Twist Lock Anchor are placed as close as possible to where the lead emerges from the deep fascia. Both have a recommended anchoring site of the supraspinous ligament or deep fascia.

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d. Tissue Securement

The current silicone rubber anchor and the Medtronic Twist Lock Anchor are secured by sutures.

e. Performance Testing

Medtronic, Inc. has provided descriptive data on the test plan and test results for the Twist Lock Anchor. These data support that the function and characteristics of the device are suitable for its intended use.

Flex testing was performed which demonstrated that the lead body, while gripped by the anchor, has equivalent flex characteristics as the lead body gripped by the current silicone anchor.

Pull testing was performed that demonstrated the breakaway load of the Twist Lock Anchor is equivalent to the current silicone rubber anchor.

In summary, Medtronic, Inc. has provided information within the 510(k) Premarket Notification to indicate that the Twist Lock anchor is safe and effective for its intended use as an alternate neurological lead accessory in the treatment of chronic intractable pain of the trunk and limbs. Additionally, the Twist Lock Anchor has been shown to be comparable in terms of intended use and technological characteristics to the silicone rubber anchor currently in commercial distribution. The data and information provided within the 510(k) Premarket Notification adequately support that the Twist Lock Anchor is substantially equivalent to the silicone rubber anchor currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa L. Pritchard
Senior Product Regulation Manager
Medtronic, Inc.
800 53rd Avenue NE
P.O. Box 1250
Minneapolis, Minnesota 55440-9087

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Re: K972906
Medtronic Twist Lock Anchor
[Part 103963, or Model 3550TLA]
Regulatory Class: II
Product Code: GZB
Dated: December 30, 1997
Received: December 31, 1997

Dear Ms. Pritchard:

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 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 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) 594-4659. 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" (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,

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

Enclosure

510(k) Number (if known)_____

Device Name: Twist Lock Anchor

Indications for Use:

The Medtronic Twist Lock Anchor, Part Number 103953 or Model 3550TLA, is indicated as an alternate anchor accessory for use with Spinal Cord Stimulation (SCS) Systems for the treatment of chronic intractable pain of the trunk or limbs. The Twist Lock Anchor is only for use with coiled conductor Medtronic Neurological Spinal Cord Stimulation leads with an outside diameter of 1.27 mm. All other uses are contraindicated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972906

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)