K972814

ST. JUDE MEDICAL
CARDIAC RHYTHM MANAGEMENT DIVISION

15900 Valley View Court
Sylmar, CA 91342
818 362-6822
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FEB 23 1998

510(K) SUMMARY

Name of Sponsor: Pacesetter, Inc., A St. Jude Medical Company

Sponsor Address: 15900 Valley View Court
PO Box 9221
Sylmar, CA 91392-2991
(818) 362-6822

Contact: Ana Wood 12/5/97
Ana Wood Date

Date of Summary Preparation: December 3, 1997

Name of Device: Proprietary - The Locator™
Common Name - steerable stylet

Classification: 74DTB - accessory to permanent pacemaker electrode
Class III - Division of Cardiovascular, Respiratory and Neurological Devices

Predicate Devices: Pacesetter ball-tipped stylets - straight and j-shaped

Device Description: The Locator™ steerable stylet consists of a curved wire that fits inside a thin-walled tube. Sliding the tube relative to the wire by manipulating the handle allows different curvatures on the stylet, and thus the lead, to be obtained.

Intended Use:
- To facilitate advancement of the lead in the vasculature
- To allow control the shape of the lead without removing the stylet from the lead

Nonclinical Testing: Both preclinical and qualification testing of the Locator™ indicate that this device is substantially equivalent with regard to safety and effectiveness to a marketed device.

Clinical Testing: No clinical testing was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 1998

Ms. Ana Wood
St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, CA 91392-9221

Re: K972814
Locator™ Steerable Stylet, Model 4036
Regulatory Class: III (three)
Product Code: DTB
Dated: December 5, 1997
Received: December 8, 1997

Dear Ms. Wood:

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 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 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: K972814

Device Name: The Locator™ Steerable Stylet

Indication for Use: The Locator™ Steerable Stylet is intended for use when implanting the Pacesetter Tendril® model 1188 T/K pacemaker leads, in 46, 52, and 58 cm lengths in patients requiring long-term lead implantation to provide cardiac pacing.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972814

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over The Counter Use ____
(Optional Format 1-2-96)