

K970853
P12

Summary of Safety and Effectiveness

NOV - 4 1997

Trade Name:

Cardima Pathfinder 3mm Mapping Microcatheter

Manufacturer:

Cardima, Inc.
47266 Benicia Street
Fremont, CA 94538-7330
Contact: Jack P. Douglas, Ph.D.
Establishment Registration Number: 9007594

Classification Name:

Electrode Recording Catheter (21 CFR 870.1220)

Device Classification:

Class II (21 CFR 870.1220) Panel: Circulatory System Devices Panel, DCRND

Intended Use and Product Description:

The Cardima Pathfinder® 3mm Mapping Catheter is a diagnostic medical device designed to provide localized unipolar or bipolar sensing of electrical potentials in the heart. The catheter is available with 4 or 8, 3mm long electrodes spaced 2mm apart providing for a total electrode recording length of 4cm. The working outer diameter of the catheter is 3.3F and will be available with useable lengths of 100cm and 135cm. The Pathfinder is also indicated for pacing. It is contraindicated for ablation. The outer surface is treated with a hydrophilic coating to enhance lubriciousness.

Sterilization, Packaging and Pyrogenicity:

The Pathfinder 3mm Mapping Catheter is packaged individually in a polyethylene protective coil. Each coil is in turn placed in a clear, blue tinted tray and a translucent-white Tyvek lid that is heat sealed to the outside of the tray. This sealed tray is placed within a standard Tyvek/polyester-polyethylene pouch which is also heat sealed. All product is sterilized using gamma radiation.

Substantial Equivalence:

The Pathfinder 3mm Mapping Catheter is a modified version of Cardima's 2.5F Pathfinder electrode recording catheter. Establishment of equivalence was based on similarities of labeling, design, materials, and physical characteristics as evaluated by physical bench testing and biocompatibility. Design modifications include a longer electrode length and a larger outer diameter size.

Summary of Safety and Effectiveness:

Safety and effectiveness were evaluated through biocompatibility testing, reliability testing and animal studies. Biocompatibility testing was conducted on final sterilized Pathfinder product per ISO 10993-1 and shown to be acceptable for all categories. Reliability testing was conducted on sterilized product per "Electrode Recording Catheter Preliminary Guidance, March 1995". The tests were used to assess the mechanical and electrical properties of both the catheter and the connector cable and found to be acceptable for use.

Animal studies were conducted to evaluate the maneuverability and signal quality of the Pathfinder 3 mm catheter positioned in the coronary sinus, right atrium and right ventricle. The catheter could be positioned into the coronary sinus, right atrium and right ventricle without significant difficulty, and signals were of good quality and adequate for clinical applications. Pacing was easily achieved at clinically-relevant thresholds. During one study, coronary sinus thrombosis occurred in one animal, believed to result from manipulation of the guiding catheter. Otherwise, this procedure was found to be safe without injury to the animals.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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Jack P. Douglas, Ph.D.
Regulatory Affairs Manager
Cardima, Inc.
47266 Benicia Street
P.O. Box 14172
Fremont, California 94539-1372

Re: K970853
Trade Name: Cardima Pathfinder 3mm Mapping Microcatheter™
Regulatory Class: II
Product Code: 74DRF
Dated: August 5, 1997
Received: August 7, 1997

Dear Dr. Douglas:

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 (Pre-market 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 pre-market notification submission does not affect any

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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 at (301) 443-6597.

Sincerely yours,



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): K970853

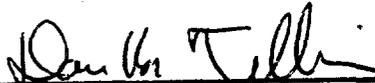
Device Name: **Cardima Pathfinder 3mm Mapping Microcatheter**

Indications For Use:

The Cardima Pathfinder 3mm catheter is intended for electrogram recording and pacing during diagnostic electrophysiology studies.

(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 K970853

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)