K971975

JUL 1 1998

Summary of Safety and Effectiveness

Trade Name:

Cardima Pathfinder 1.5F 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® 1.5F Mapping Catheter is a diagnostic medical device designed to provide localized unipolar or bipolar sensing of electrical potentials as measured from within the venous system of the heart. The catheter is available with 4, 1mm long electrodes spaced either 2mm or 2-6-2mm apart providing for a total electrode recording length of 10-14 mm. The working outer diameter of the catheter is 1.5F and will be available with working lengths of 135cm and 170cm. The Pathfinder is not indicated for pacing or ablation. The outer surface is treated with a hydrophilic coating to enhance lubriciousness.

Sterilization, Packaging and Pyrogenicity:

The Pathfinder 1.5F 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 1.5F 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. The primary design modification involves a change of outer diameter from 2.5F to 1.5F.

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 1.5F catheter positioned in the coronary sinus and veins. The catheter was shown to be easily positioned into selected coronary veins including the anterior interventricular, middle cardiac, posterolateral, lateral and anterolateral veins without difficulty, and signals were of good quality and adequate for clinical applications. Effusion of dye outside the coronary venous system was not evident, nor was there pericardial effusion found on gross examination of the heart. Some procedural complications noted most likely attributable to the guiding catheter included slight endothelial injury with consequent thrombus formation in one case. Some small subepicardial hemorrhage was found around the proximal middle cardiac vein in 2 dogs, and the coronary sinus area in 2 dogs. These complications are not considered to be clinically significant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 1998

Jack P. Douglas, Ph.D.
Director of Regulatory Affairs
Cardima, Inc.
47266 Benicia Street
P.O. Box 14172
Fremont, CA 94538-7330

Re: K971975
Cardima Pathfinder™ 1.5F Mapping Microcatheter
Regulatory Class: II (two)
Product Code: DRF
Dated: April 7, 1998
Received: April 8, 1998

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 (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 (if known): K971975

Device Name: Cardima Pathfinder 1.5F Mapping Microcatheter ™

Indications For Use:

The Cardima Pathfinder 1.5F Microcatheter is intended for electrogram recording from within the coronary venous system 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 K971975

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)