

MAY 11 1999

K972803

Summary of Safety and Effectiveness

Trade Name:

Cardima Tracer Over-the-Wire Mapping Microcatheter

Manufacturer:

Cardima, Inc.
47266 Benicia Street
Fremont, CA 94538-7330
Contact: Shelley Trimm
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 Tracer Over-the-Wire Mapping Microcatheter 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 Tracer catheter can also be utilized for temporary epicardial pacing during the mapping procedure. The catheter is designed to accommodate a 0.010" guide wire and is available in five configurations with either 4, 8, or 16 electrodes. Both the 4 and 8 electrode catheters come with either regular spaced electrodes of 5mm or electrode pair spacing of 2-5-2 mm. The 16 electrode catheter is available only with 2-5-2mm pair spacing. The outer diameter of the catheter is 3.2F - 3.3F and will be available with working lengths of 145cm. The outer surface is treated with a hydrophilic coating to enhance lubriciousness. The Tracer is not indicated for ablation.

Sterilization, Packaging and Pyrogenicity:

The Tracer is packaged individually as a coil in a clear, blue tinted polyethylene terephthalate (PETG) tray which is heat-sealed with a translucent-white Tyvek lid. This sealed tray is placed within a standard Tyvek/polyester-polyethylene pouch which is also heat sealed. Both Tracer and Pathfinder utilize the identical packaging materials and process for gamma sterilization. The design modification to Tracer does not introduce any new or unique challenges to the current validate sterilization process. Given these considerations re-validating the sterilization process used for Tracer was deemed unnecessary.

Substantial Equivalence:

The Tracer Over-the-Wire Mapping Catheter is a modified version of Cardima 2.5F Pathfinder electrode recording catheter (cleared K955802). Establishment of equivalence was based on similarities of labeling, design, materials, and physical characteristics as evaluated by physical bench testing, biocompatibility and animal studies. The primary design modification involves use of an over-the-wire feature and a larger outer diameter. The additional intended for use claim: "can be utilized for temporary pacing", was supported by the animal studies.

Summary of Safety and Effectiveness:

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

Animal studies were conducted to evaluate the maneuverability and signal quality of the Tracer positioned in the coronary sinus and coronary veins. The Tracer catheter was also evaluated for pacing. The catheter could be positioned into the coronary sinus and distal coronary veins without difficulty. Signals were of good quality and adequate for clinical applications. Ventricular pacing from different pairs of electrodes on the Tracer were conducted on twelve occasions (threshold 0.1 - 1.9 mA @ a pulse width of 2.0 msec.). Coronary sinus angiography post-procedure showed normal venous anatomy without rupture or thrombosis. Effusion of dye outside the coronary venous system was not evident, nor was pericardial effusion found on gross examination of the heart. In two cases small patches of subepicardial hemorrhage were found on post-mortem inspection, and are believed to be clinically insignificant.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K972803
Cardima® TRACER™ Over-the-Wire Mapping Microcatheter
Regulatory Class: II (two)
Product Code: DRF
Dated: March 1, 1999
Received: March 2, 1999

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 legally marketed predicate 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 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" (21CFR 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/dsma/dsmamain.html>".

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): K972803

Device Name: Tracer Over-the-Wire Mapping Microcatheter

Indications For Use: The Tracer diagnostic mapping device is intended for use in cardiac electrophysiology studies. This catheter can be used to temporarily record epicardial electrical signals from the coronary sinus. The Tracer catheter can be used to temporarily pace during the mapping procedure.

(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 K972803

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____