

SECTION 4.0: 510(K) SUMMARY

INDICATIONS

The Mercator Atrial High Density Array Catheter is intended to be used in the right atrium of patients with complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). When used in conjunction with electrogram recording equipment and stimulators, the system is used to record intracardiac electrogram (EGM) signals and to deliver pacing pulses for the purpose of diagnostic provocative stimulation during an electrophysiology procedure.

The Mercator Atrial High Density Array Catheter can be used with:

- the Cardiac Pathways' Model 8100 Arrhythmia Mapping System and the Model 8300 Signal Acquisition Module in conjunction with a stimulator, and
- Cardiac Pathways' EGM Adapter Cables (Models 2036, 2043, and 2044) in conjunction with intracardiac electrogram recording equipment.

DEVICE DESCRIPTION

The Mercator High Density Array Catheter has an 8.5F catheter shaft with a collapsible, spheroid-shaped, 32-bipole-electrode array (64 electrodes) on the distal end, and an integrated cable/connector assembly on the proximal end. The device is designed to connect/mate directly with the Cardiac Pathways' Arrhythmia Mapping System and with Cardiac Pathways' EGM Adapter Cables. The EGM Adapter Cables can be connected to electrogram recording equipment.

The Mercator High Density Array Catheter has been described previously in the 510(k) Summary and the Device Description section in the 510(k) submission file number K982540.

There are three different EGM Adapter Cables for use with the Mercator Catheter. The distal end of the cable is identical in each of the three cable types and defined as the end that connects to the Mercator High Density Array Catheter. The proximal end connects to electrogram recording equipment.

The distal end of the EGM Adapter Cables is a threaded-body style connector that has contacts for each of the 64 electrodes of the Mercator High-Density Array Catheter and a contact for a shield wire. The proximal end of the cable distinguishes the three EGM Adapter Cables. The Model 2036 EGM Adapter Cable allows for general connection of individual electrodes to electrogram recorders and stimulators. This cable has 64 independent connectors on the proximal end. Model 2043 and Model 2044 EGM Adapter Cables have connector configurations that can mate with Prucka CardioLab recording systems. These cables have two connectors on the proximal end. On each of these two connectors, 33 contacts connect 32 electrodes and 1 shield wire from the Mercator High-Density Array Catheter to the inputs on the Prucka system. The two Prucka connector cable

models differ in that one model has pin-type contacts and the other model has socket-type contacts to adapt to suitable models of the Prucka recording system. The EGM Adapter Cables are not sterilized since they are not in the sterile field during a procedure.

PREDICATE DEVICES

The Mercator Atrial High Density Array Catheter when used in conjunction with the EGM Adapter Cables is substantially equivalent to the Mercator Atrial High Density Array Catheter.

PERFORMANCE DATA

The Mercator Atrial High Density Array Catheter was subjected to a battery of testing (bench, animal, and clinical) that has been described previously in the 510(k) Summary for the 510(k) submission file number, K982540.

The EGM Adapter Cables were subjected to electrical and mechanical tests to verify that the devices met the specifications. Electrical testing included, but was not limited to: assessment for continuity and short circuits, capacitance, dielectric strength and current leakage, noise, and cross-talk. The device met the specifications. Mechanical testing included, but was not limited to: assessment of joint strengths and the forces required to engage and separate the devices. The device met the specifications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 1999

Ms. Erin Dignan
Manager, Regulatory Affairs
Cardiac Pathways Corporation
995 Benecia Avenue
Sunnyvale, CA 94086

Re: K990795
Mercator Atrial High Density Array Catheter and Cardiac
Pathways EGM Adapter Cables
Regulatory Class: II (two)
Product Code: MTD
Dated: March 9, 1999
Received: March 10, 1999

Dear Ms. Dignan:

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

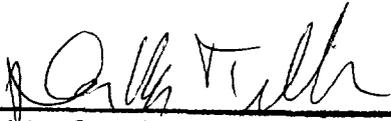
SECTION 2.0: INDICATIONS

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Prescription Use
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990795