JAN 27 1999

K982540

APPENDIX F

REVISED 510(K) SUMMARY
FOR THE
MERCATOR ATRIAL HIGH DENSITY ARRAY CATHETER

510(k) SUMMARY

Indications

The Mercator Atrial High–Density Array Catheter, used in conjunction with the Cardiac Pathways' Model 8100 Arrhythmia Mapping System and the Model 8300 Signal Acquisition Module, is intended to be used in the right atrium of patients with complex arrhythmias to record intracardiac electrogram (EGM) signals and to deliver pacing pulses for the purpose of diagnostic provocative stimulation during an electrophysiology procedure.

Device Description

The Mercator High Density Array Catheter has an 8.5F catheter shaft with a collapsible, spheroidal–shaped, 32 bipole electrode array on the distal end, and an integrated cable/connector assembly on the proximal end. The device is designed to interface with the Cardiac Pathways' Arrhythmia Mapping System. There are three sizes of arrays for the right atrium based on the atrial volume derived from transthoracic echocardiograms: 70 cc, 100 cc, and 130 cc.

The electrode array consists of eight equidistant arms fixed at each end to form a spheroid. The arms terminate into an atraumatic tip on the distal end, and transition into the catheter shaft on the proximal end. The arms are made of a compliant material that maintains contact against the atrial walls during the cardiac cycle. The arms are labeled A through H in a clockwise direction. The array orientation is ascertained using three radiopaque markers positioned on arms A (distal), B (mid) and C (proximal). Each arm has four electrode pairs spaced equidistant from each other along the length of each arm. Each electrode is 0.75 mm wide by 0.25 mm high. The electrode spacing is the same for all three sizes of catheters; 1 mm between electrodes in a bipole and 8 mm between bipoles when measured center to center.

The electrical connections between the electrodes on the array and the connector on the proximal end of the catheter are made via cables. The cables run the length of the catheter shaft and connector bump tubing. The catheter shaft terminates at the proximal end at the Y–arm assembly. The center lumen of the catheter is contiguous with the luer fitting on the straight arm of the Y–arm assembly and is used for flushing the catheter. The angled arm on the Y–arm assembly provides the interface for the connector bump tubing.

The connector has 79 pins, and interfaces with a mating receptacle on the Arrhythmia Mapping System. The terminations of the cables at the connector are housed inside a backshell that provides a smooth transition from the connector to the connector bump tubing.

The 11 F Guiding Sheath and the 30° Angled Guiding Sheath have an 11 F braided catheter shaft that terminates into a short, atraumatic tip on the distal end and a luer fitting on the proximal end. On the 30° Angled Guiding Sheath, the distal 4.5 cm of the catheter shaft is angled 30° from the proximal shaft of the catheter. The 11 F Guiding Sheath and the 30° Angled Guiding Sheath are used in conjunction with the 8.5 F Pigtail Catheter and the 30° Angled 8.5 F Pigtail Catheter, respectively, to position the High Density Array Catheter in the right atrium.

The 11 F Guiding Sheaths have a large inside diameter through which the High Density Array Catheter is inserted into and withdrawn from the cardiovascular system. The shaft of the Guiding Sheath is radiopaque. The Guiding Sheath terminates into a female luer fitting on the proximal end. This luer fitting is used to flush the Guiding Sheath and to introduce the High Density Array Catheter into the Guiding Sheath. The working length of the Guiding Sheath is 110 cm.

The purpose of the Guiding Sheath is to "guide" the High Density Array Catheter to a position in the right atrium found using the 8.5 F Pigtail Catheter. The Guiding Sheath is also used to collapse and withdraw the electrode array on the High Density Array Catheter when mapping is complete

The 8.5 F Pigtail Catheter and the 30° Angled 8.5 F Pigtail Catheter have an 8.5 F braided catheter shaft on the proximal end attached to a soft distal extrusion that is necked down and formed into a radius known as a "pigtail". The 8.5 F Pigtail Catheter and the 30° Angled 8.5 F Pigtail Catheter are used in conjunction with the 11 F Guiding Sheath to position the High Density Array Catheter in the right atrium.

The Pigtail Catheters have an open center lumen and 12 side holes positioned equidistant from each other in the distal extrusion, proximal to the pigtail. These holes can be used to deliver contrast media into the right atrium for visualization of catheter position and to assess the size of the atrium. The center lumen is accessible for flushing using a female luer lock fitting on the proximal end of the Pigtail Catheter. The braided shaft is radiopaque and gives the catheter good torque transmission.

The diameter of the pigtail tip is 1.3 cm. The purpose of this large diameter tip is to facilitate atraumatic placement into the right atrium. It also helps to avoid prolapsing of the High Density Array Catheter through the tricuspid valve into the right ventricle. The working length of the Pigtail Catheter is 135 cm.

A pigtail stylet is packaged in the Deployment Kit to straighten out the distal radius of the pigtail when inserting it inside the Guiding Sheath. The stylet is a stainless steel mandrel with a ball on the end to prevent advancing it all the way into the center lumen of the Pigtail Catheters. The pigtail stylet is used only in the preparation of the Guiding Sheath/Pigtail Catheter assembly and is not intended to be inserted into a patient. It is removed after the Pigtail Catheter is positioned inside the Guiding Sheath.

Predicate Devices

The Mercator Atrial High Density Array Catheter is substantially equivalent to Woven Dacron® Electrode Catheters and Atrial Mapping Electrode Catheters manufactured by Bard Electrophysiology, the Explorer ST™ Fixed Curve Diagnostic Catheter manufactured by EP Technologies, and Fixed Tip Electrophysiology Catheters and the Deflectable Halo Electrophysiology Catheters manufactured by Webster Laboratories.

Performance Data

The Mercator Atrial High Density Array Catheter, the Guiding Sheaths, and the Pigtail Catheters were subjected to a battery of electrical and mechanical tests to verify that the devices met the specifications. Electrical testing included, but were not limited to, assessment for continuity and short circuits, DC impedance, AC impedance, capacitance, and dielectric strength and current leakage. The device met the specifications. Mechanical testing included, but was not limited to, assessment of joint strengths and the forces required to insert and withdraw the devices. The device met the specifications. Biocompatibility testing was performed to verify that the devices did not elicit toxicological responses.

Clinical testing was performed in accordance with an Investigational Device Exemption granted by the FDA. A total of 79 patients were enrolled in this study at eight centers. A total of 74 patients were included in the data analysis; five patients were excluded from analysis because the HDAC was not deployed in the heart. The patient population had a mean age of 51.6 years, and the gender distribution was 54% male and 46% female. Fifty-one percent of patients had a history of atrial flutter or fibrillation. The majority of patients (55%) had other co-existing chronic conditions. Thus, the patients in this study were somewhat older than a typical supraventricular tachycardia population. The most common arrhythmia study diagnoses were atrial flutter in 30%, atrioventricular nodal tachycardia in 18%, supraventricular tachycardia in 18%, and atrial tachycardia in 16% of patients. The electrophysiology procedure included the performance of radiofrequency catheter ablation in 88% of patients, and was considered acutely successful in 89% of those undergoing ablation.

A total of 92 HDACs were deployed in 74 patients. The selection of HDAC size was based in part upon measurements of end-systolic right atrial dimensions obtained from the pre-procedure echocardiogram. Larger HDAC sizes were used in patients with larger right atrial dimensions. In patients with normal right atrial dimensions, the 70 cc HDAC was always chosen.

Atrial pacing capture was determined for each bipole pair at 2 mA and at 5 mA. Consistent capture of one or more bipole pairs at 5 mA was achieved in 96.9% of patients.

The primary analyses of equivalence between the HDAC and predicate devices (diagnostic commercial catheters) were performed by a blinded independent expert. The analyses involved comparing electrograms from both devices in sinus rhythm and the atrial arrhythmia.

Electrogram recordings were obtained during sinus rhythm with standard catheters in 88% of patients and with the HDAC in 82% of patients. Recordings were obtained during the atrial arrhythmia in 81% of patients with standard catheters and in 78% of patients with the HDAC.

Matched sets of electrogram data in sinus rhythm for both standard catheters and the HDAC were available for analysis by the independent expert for 41 patients. The overall diagnostic quality in sinus rhythm was rated as identical ($p = 1.000$). With both devices, recordings were acceptable to make a diagnosis of sinus rhythm in all patients. The rhythm diagnosis was sinus rhythm in all cases with both devices. The overall signal quality was rated as similar ($p = 0.8643$).

Matched sets of electrogram data in the atrial arrhythmia for standard catheters and the HDAC were available for analysis by the independent expert for 45 patients. The overall diagnostic quality was rated as similar ($p = 0.1177$). The recordings were acceptable to make a diagnosis of atrial arrhythmia in all patients with standard catheters and the HDAC. Using predefined diagnostic categories, the arrhythmia diagnoses were similar with the two devices (Kappa = 0.799). The overall signal quality also manifested no difference among catheters ($p = 0.4559$).

Baseline noise was evaluated by the independent expert, who measured the peak-to-peak absolute amplitude of noise on individual signals. The mean baseline noise recorded per electrode pair was 0.016 ± 0.075 mV for standard catheters and 0.019 ± 0.096 mV for the HDAC ($p = 0.5450$). The proportion of electrode pairs with baseline noise recorded was 7.6% for standard catheters and 6.8% for the HDAC. The mean baseline noise recorded for each patient was also similar for both devices ($p = 0.8970$). Regardless of the way in which absolute peak-to-peak noise was compared, the standard catheter and HDAC were equivalent.

Patients were anticoagulated using intravenous heparin, and activated clotting time (ACT) levels were used to guide heparin administration. The mean baseline ACT was 126.0 ± 20.7 sec, and the mean ACT on heparin was 257.0 ± 52.2 sec. The mean ACT level using linear regression analysis was stable over time, achieving a range of 1.5-2.5 times the baseline value.

Safety was evaluated based upon the findings of the pre-discharge echocardiogram, the pre-discharge history and physical examination, and the examination of the HDAC immediately after removal. There were no instances of thromboembolic events, cardiac perforation, or valve injury. There was no evidence of thrombus on the 92 HDAC

catheters visually inspected immediately following removal from the patient. One procedure-related major adverse event (1.35%) occurred involving a left femoral hematoma in a patient in whom the HDAC was inserted into the right femoral vein. Three minor, procedure-related adverse events occurred, one case of transient Type I (Wenckebach) AV block and pleuritic chest pain, one case of chest pain probably related to radiofrequency catheter ablation, and a third case of oropharyngeal edema attributed to an allergic reaction from a sedative used during the procedure.

In conclusion, the data supports the comparability of the HDAC with standard (linear) diagnostic electrophysiology catheters. Specifically, the ability to make an arrhythmia diagnosis in all cases with either catheter, similar diagnostic quality, similar rhythm interpretations, similar signal quality, and similar absolute baseline noise. The functionality was adequately defined regarding pacing and recording capabilities. The HDAC demonstrated an excellent safety profile compared to comparison groups of patients undergoing either diagnostic electrophysiology studies or radiofrequency catheter ablation for supraventricular tachyarrhythmia with standard linear mapping. The three sizes and shapes of the HDAC appeared appropriate for the intended patient population. The data supports the use of the HDAC as a diagnostic tool for the recording of multiple intracardiac electrograms and delivery of pacing stimuli to the right atrium.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 1999

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

Re: K982540
Mercator™ Atrial High Density Array Catheter
Regulatory Class: II (two)
Product Code: MTD - High density array intracardiac mapping catheter
Dated: October 28, 1998
Received: October 29, 1998

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 and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

WARNING: The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

The Warning must be presented within a black box, and the font size of the text should be at least 2 points larger than any surrounding text. The Warning must be present on the first page of your Operator's Manual, and on the packaging for each individual device.

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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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/dsma/dsmamain.html".

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982540

Device Name: Cardiac Pathways Mercator ™ Atrial High Density Array Catheter

FDA's Statement of the Indications For Use for device:

The Mercator Atrial High-Density Array Catheter, used in conjunction with the Cardiac Pathways' Model 8100 Arrhythmia Mapping System and the Model 8300 Signal Acquisition Module, 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). 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.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K982540

Prescription Use XX OR Over-The-Counter Use
(Per 21 CFR 801.109)