RHYTHMIA medical

1 510(k) Summary

APR 18 2013

1.1 General Information

Date Compiled April 15, 2013

Classification Class II, 21 CFR § 870.1220, Electrode Recording Catheter or Electrode Recording Probe, Product Code DRF (Catheter, Electrode Recording, or Probe, Electrode Recording)

Trade Name Rhythmia Mapping Catheter

Model Number RM-C00101: Rhythmia Mapping Catheter

Submitter
Rhythmia Medical, Inc.
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1.2 Intended Use

The Rhythmia Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

1.3 Predicate Device

Desai VectorCath™ Mapping Catheter K011361

Manufactured by CathEffects

1.4 Engineering Part Number

The Rhythmia Mapping Catheter Model ID RM-C00101 is being referred to in most engineering documents as part number **RM400-012**.

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1.5 Device Description

The Rhythmia Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. The Rhythmia Catheter is an 8.5 French (2.8mm), 115 cm, bidirectional, 64 electrode, non-linear (basket shaped) diagnostic catheter. The catheter consists of a polymer handle, a polymer shaft and a platinum/iridium and polymer distal mapping section mounted with iridium electrodes ('electrode array'). The catheter contains a flushing port capable of providing continuous flushing into the electrode array. The catheter is supplied with an 8.5 French insertion sleeve for insertion through the hemostasis valve of an introducer sheath. The catheter is provided sterile and is for single use only.

The Rhythmia Catheter simultaneously acquires 64 electrograms from the electrodes on its splines. The catheter is designed to enter the vasculature with a low profile (8.5F) through a percutaneous approach. The catheter can be maneuvered with the aid of a handle that controls bidirectional steering and array deployment. The catheter can be connected to commercially available EP diagnostic systems such as recording systems or 3D mapping systems.

1.6 Testing

In vitro testing was performed on the Rhythmia Mapping Catheter to assure reliable design and performance in accordance with ISO 10555-1:2004. The bench tests performed by the company included Physical Dimensions, Essential Catheter Features, Array Stiffness, Handle Control Forces, Compatibility with Sheaths, Array Shape Reproducibility, Radiopacity, Flushing Flow Rate, Labeling Content, Surface Inspection, Leak and Fluid Ingress Resistance, Corrosion Resistance, Joint Strengths, Catheter Tip Flexibility, Catheter Torsion Resistance, Catheter Kink Resistance, Simulated Use Bench Test, Particulate Evaluation, Spline Fatigue Cycling and Strength, Array Shape Resilience, Pigtail Performance, Labeling Durability, Handle Marking Content and Durability, Connector Mate Life, Connector Latch Holding Force, Catheter Electrical Performance, Catheter Memory Function, Compatibility with Third-Party Recording Systems, Catheter Defibrillation Survival, and Electrical Cross-Talk. The test results demonstrate that the Rhythmia Mapping Catheter meets the requirements in the applicable standards and specifications, and is substantially equivalent to the legally marketed predicate device.

1.7 In vivo testing

Design validation of the catheter was performed in a GLP animal study designed to determine the catheter's ability to safely access, maneuver, stimulate and record electrical signals in the cardiac chambers as intended. The GLP study met the predefined endpoints in terms of safety and performance.

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1.8 Clinical experience

A clinical evaluation was performed outside the US using the Rhythmia Mapping Catheter. Twenty-nine (29) subjects were enrolled in 3 sites. There were no adverse events related to the Rhythmia Mapping Catheter, and the catheter performed as intended.

1.9 Summary of Substantial Equivalence

Rhythmia Medical believes the Rhythmia Mapping Catheter is substantially equivalent to the predicate product and is as safe, as effective, and performs as well as or better than the predicate device. The indications for use, intended use, product function, design and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 18, 2013

Rhythmia Medical, Inc.
c/o Mr. Leon Amariglio
Co-CEO
111 South Bedford Street, Suite 205
Burlington, MA 01803

Re: K122461
Trade/Device Name: Rhythmia Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Catheter, Electrode Recording, or Probe, Electrode Recording
Regulatory Class: Class II (two)
Product Code: DRF
Dated: April 4, 2013
Received: April 5, 2013

Dear Mr. Amariglio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, MD
Division Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4 Indications for Use Statement

510(k) Number (if known): This application

Device Name: Rhythmia Mapping Catheter

Indications for Use: The Rhythmia Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

Prescription Use _X_ AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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