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Section 14

Summary Of Safety And Effectiveness

AUG 13 2010

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

a. Submitter: Irvine Biomedical, Inc.
a St. Jude Medical Company
2375 Morse Avenue
Irvine, CA 92614
Tel. (949) 769-5000

b. Contact Person: Quynh Phuong Le
Regulatory Affairs Specialist II
Tel. (949) 769-5058

c. Date Summary Prepared: June 8, 2010

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Inquiry™ AFocusII™ Diagnostic Catheter

b. Classification names: Catheter, Electrode Recording

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company: Irvine Biomedical, Inc
a St. Jude Medical Company
Device: Inquiry™ AFocusII™ Steerable Electrophysiology Catheter
510(k): K042775
Date Cleared: November 4, 2004

Company: St. Jude Medical
Device: Reflexion HD™ High-Density Mapping Catheter
510(k): K080179
Date Cleared: January 7, 2009

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4. **A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The Inquiry™ AFocusII™ Diagnostic Catheter is a flexible, radiopaque catheter with a variable number of electrodes with the first electrode located at the distal tip and the other band electrodes following at predetermined distances. A connecting cable is used to connect the catheter to electrogram devices.

The catheter has a distal double loop in a plane perpendicular to the catheter body. The circumferential shape or loop allows the electrophysiologist to record the potentials of cardiac structures without changing the position of the catheter. The catheter shaft is steerable by manipulating the handle. The placement of the electrodes around the entire circumference of the distal loop also assists the electrophysiologist during fluoroscopy with visualization. The distal loop shape is easily straightened with the thumb and forefinger to facilitate insertion into sheaths and introducers. Once the catheter is extended beyond the sheath, the catheter resumes its pre-formed shape. The device is supplied sterile and is intended for single use only.

5. **Statement of intended use:**

The Inquiry™ AFocusII™ Diagnostic Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiological studies. The Inquiry™ AFocusII™ Diagnostic catheters are to be used to map the atrial regions of the heart.

6. **Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

The Inquiry™ AFocusII™ Diagnostic Catheter and its predicate devices are intended for electrogram recording and stimulation during electrophysiological studies. The modifications do not affect the intended use or scientific technology of the device, as embodied in the catheter.

7. **Brief summary of nonclinical tests and results:**

The bench testing for the Inquiry™ AFocusII™ Diagnostic Catheter was based on the guidance document "Electrode Recording Catheter Preliminary Guidance, Draft Version", March 1995. Test results indicate reliable performance when the device is used in accordance with the Instructions for Use. The catheter does not raise new issues of safety, effectiveness, or performance of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 13 2010

St. Jude Medical
c/o Ms. Quynh Phuong Le
Regulatory Affairs Specialist II
Atrial Fibrillation Division
2375 Morse Avenue
Irvine, CA 92614-6233

Re: K0101623
Trade/Device Name: Inquiry AFocusII Diagnostic Catheter
Regulatory Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: II (two)
Product Code: DRF
Dated: June 08, 2010
Received: June 09, 2010

Dear Ms. Le:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Section 13

Indications for Use

510(k) Number (if known): K101623

AUG 13 2010

Device Name: Inquiry™ AFocusII™ Diagnostic Catheter

Indications for Use:

The Inquiry™ AFocusII™ Diagnostic Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiological studies. The Inquiry™ AFocusII™ Diagnostic Catheters are to be used to map the atrial regions of the heart.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101623