K091808

SEP 10 2009

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SECTION 7

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Applicant Information:

Owner Name: Hansen Medical, Inc.
Address: 800 East Middlefield Road
Mountain View, CA. 94043
Office: 650-404-5800

Contact Person: Kate Whitin
Phone Number: 650 404 5800
Facsimile Number: 650 404 2773

Date Prepared: 8/7/2009

Device Information:

Classification: Class II
Trade Name: Hansen Medical Sensei® Robotic Catheter System
Common name: Steerable Catheter Control System
Classification name: System, Catheter Control, Steerable (21 CFR 870.1290/DXX)

Predicate Devices:

The modified Hansen Medical Sensei Robotic Catheter System is substantially equivalent in intended use and method of operation to the earlier Sensei System (K090365).

Device Description:

The Hansen Medical Sensei Robotic Catheter System and Accessories, when used in conjunction with compatible Control Catheters, are designed to facilitate manipulation, positioning and control of mapping percutaneous catheters within the atria of the heart. The fundamental concept of the system is based on a master/slave control system that enables and visualizes positioning of a steerable catheter tip at a desired point inside the heart, while

enabling a physician to remain seated and away from the x-ray radiation source. The modifications to the Sensei Robotic Catheter System include enhancements to the display of 3D electroanotomic maps from a 3rd party mapping system.

Intended Use:

The Hansen Medical Sensei® Robotic Catheter System and Accessories are intended to facilitate manipulation, positioning and control of Hansen Medical's robotically steerable catheters for collecting electrophysiological data within the heart atria with electro-anatomic mapping and recording systems, using the following percutaneous mapping catheters: the Polaris-Dx™ Steerable Diagnostic catheters made by Boston Scientific Corporation and the Livewire™ Electrophysiology catheters made by St. Jude Medical.

Comparison to Predicate Device(s):

The modified Hansen Medical Sensei Catheter Control System is substantially equivalent to the predicate device. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device.

Substantial equivalence:

Based upon the indications for use and the design and engineering data provided in this pre-market notification, the Hansen Medical Sensei Robotic Catheter System has been shown to be substantially equivalent to a currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 1 0 2009

Hansen Medical, Inc.
c/o Ms. Kate Whitin
Director, Regulatory Affairs
800 E. Middlefield Road
Mountain View, CA 94043

Re: K091808
Trade/Device Name: Hansen Medical Sensei Robotic Catheter System
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II (two)
Product Code: DXX
Dated: August 7, 2009
Received: August 10, 2009

Dear Ms. Whitin:

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). 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 labeling, on the packaging for the Artisan Steerable Guide Catheter and Sheath, on the Remote Catheter Manipulator, and the Workstation:

The safety and effectiveness of this device for use with cardiac ablation catheters, in the treatment of cardiac arrhythmias including atrial fibrillation, have not been established.

Furthermore, this warning must be prominently displayed on the Remote Catheter Manipulator, Workstation, all labeling, including pouch box, and carton labels, instructions for use and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

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 Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6

Indications for Use

510(k) Number (if known): K091808

Device Name: Hansen Medical Sensei® Robotic Catheter System

Indications for Use:

The Hansen Medical Sensei® Robotic Catheter System and Accessories are intended to facilitate manipulation, positioning and control of Hansen Medical's robotically steerable catheters for collecting electrophysiological data within the heart atria with electro-anatomic mapping and recording systems, using the following percutaneous mapping catheters: the Polaris-Dx™ Steerable Diagnostic catheters made by Boston Scientific Corporation and the Livewire™ Electrophysiology catheters made by St. Jude Medical.

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 K091808