DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 5, 2014

Hansen Medical, Inc.
Todd Milholland
Senior Manager, Regulatory Affairs
800 East Middlefield Rd
Mountain View, California 94043

Re: K141822
Trade/Device Name: Sensei X Robotic Catheter System
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: II
Product Code: DXX
Dated: July 3, 2014
Received: July 7, 2014

Dear Todd Milholland,

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Linda J. Ricci -S

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

Enclosure

SECTION 6

Indications for Use

510(k) Number (if known): K141822

Device Name: Hansen Medical Sensei® X Robotic Catheter System

Indications for Use:

The Hansen Medical Sensei X 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)

Linda J. Ricci -S

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: **To be determined**

Applicant Information:

Owner Name:	Hansen Medical, Inc.
Address:	800 East Middlefield Road Mountain View, CA. 94043 Office: 650-404-5800
Establishment Registration Number:	3006026430
Contact Person:	Todd Milholland
Phone Number:	650 404 2777
Facsimile Number:	650 404 5901
Date Prepared:	July 3, 2014

Device Information:

Regulatory Class:	Class II
Trade/Device Name:	Hansen Medical Sensei® X Robotic Catheter System
Common name:	Steerable Catheter Control System
Classification name:	System, Catheter Control, Steerable
Regulation number:	21 CFR 870.1290
Product Code:	DXX

Predicate Device:

The Hansen Medical Sensei X Robotic Catheter System is substantially equivalent in intended use and method of operation to the earlier Sensei System (Sensei X Robotic Catheter System) cleared under K102168.

Device Description:

The Hansen Medical Sensei X Robotic Catheter System and Accessories, when used in conjunction with compatible Hansen 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 X Robotic Catheter System include a series of software enhancements and a new E-Stop button.

Intended Use:

The Hansen Medical Sensei® X 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 X 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.

Technological Characteristics/Performance Data:

The Sensei X Robotic Catheter System is substantially equivalent to the predicate device in intended use, fundamental scientific technology, and performance specifications. Design verification and validation testing was performed to verify that the performance of the Sensei X Robotic Catheter System remains substantially equivalent to the predicate device. Testing performed on the modified Sensei X System included the following:

- Software Testing
- E-Stop Button functional testing
- System testing

All of the pre-determined acceptance criteria were met.

Clinical Testing:

No additional clinical evaluation of the Sensei X Robotic Catheter System is required as a result of these changes.

Substantial Equivalence:

The modified Sensei X Robotic Catheter System has the following similarities to the predicate Sensei X Robotic Catheter System cleared under K102168:

- have the same indication for use,
- have the same fundamental scientific technology,
- have the same technological characteristics, and
- have the same operating principles.

Summary:

Based on the above similarities, the Sensei X Robotic Catheter System subject to this submission is substantially equivalent to the predicate device.