K132369

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: Hassan Labay
Phone Number: 650 404 5888
Facsimile Number: 650 404 2773

SEP 27 2013

Date Prepared: 9/26/2013

Device Information:

Classification: Class II
Trade Name: Hansen Medical Magellan™ Robotic System;
Magellan™ Robotic Catheter 9Fr (*Formerly known as NorthStar™ Robotic Catheter*)
Common name: Steerable Catheter Control System;
Steerable catheter
Classification name: System, Catheter Control, Steerable (21 CFR 870.1290/DXX);
Catheter, Steerable (21 CFR 870.1280/DRA)

Predicate Devices:

The modified Hansen Medical Magellan System (Magellan Robotic System and the Magellan Robotic Catheter 9Fr), is substantially equivalent in intended use and method of operation to the cleared Magellan System (Magellan Robotic System and Magellan Robotic Catheter 9Fr) cleared under K111004.

Device Description:

The Hansen Medical Magellan Robotic System and Magellan Robotic Catheter 9Fr and Accessory Components are designed to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices. 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 vasculature, while enabling a physician to remain seated and away from the x-ray radiation source. The modifications to the Magellan System were made to expand system-guide wire compatibility, provide alternate guide wire navigation using the Master Input Device in addition to the existing Workstation and Bedside Controllers and to provide support for future compatible Hansen vascular catheters.

Intended Use:

Magellan Robotic System: The Hansen Medical Magellan Robotic System and accessory components are intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

The Magellan Robotic System is intended to be used with compatible Hansen Medical robotically steerable catheters.

Magellan Robotic Catheter 9Fr: The Hansen Medical Magellan Robotic Catheter 9Fr is intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

The Magellan Robotic Catheter 9Fr is intended to be used with the Hansen Medical Magellan Robotic System and accessories.

Summary of Technological Characteristics in Comparison to Predicate Device:

The Magellan System is substantially equivalent to the predicate device. The Magellan Robotic System software modifications to expand system-guide wire compatibility, to enhance user interface and clinical procedural workflow and to expand system support for an additional Hansen Medical vascular control catheter do not affect the intended use of the device or alter the fundamental scientific technology associated with the device. Both the proposed and predicate device facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual

placement of therapeutic devices, while allowing the physician to perform the procedure from a position beyond the radiation filed.

Substantial equivalence:

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

Summary of Non-Clinical Testing:

Design verification and validation testing was performed to ensure that the Magellan System met design specifications and customer requirements. Testing activities included software and catheter verification and validation tests. Verification and Validation testing includes the following:

- System Set Up Test
- Catheter Installation Test
- System -Guide Wire Compatibility Test
- Procedure Simulation (Catheter and Guide Wire navigation) Test
- Magellan Catheters Drive Modes
- User Interface Test
- 3D Controller Test
- System Status and Error Message Test
- System Power Cycle Test
- Emergency and Configuration Tests
- Electrical Safety Test

Risk analysis activities were completed based on ISO 14971.

Summary of Clinical Testing:

No additional clinical evaluation of the Magellan System is required as a result of these changes.

Substantial equivalence:

The modified Magellan Robotic System and Magellan Robotic Catheter 9Fr have the following similarities to the predicate devices which previously received clearance under K111004.

- have the same indication for use,
- have the same fundamental scientific technology,
- incorporate the same catheter design,
- catheter incorporate the same materials, and
- catheter uses the same sterilization processes.

In summary, the Magellan System (Magellan Robotic System and the Magellan Robotic Catheter 9Fr) subject to this submission is substantially equivalent to the predicate device.

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

September 27, 2013

Hansen Medical, Inc.
Hassan Labay
800 East Middlefield Road
Mountain View, CA 94043 US

Re: K132369
Trade/Device Name: Magellan Robotic System, Magellan Robotic Catheter 9Fr
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System, Steerable Catheter
Regulatory Class: Class II
Product Code: DXX, DRA
Dated: August 28, 2013
Received: August 29, 2013

Dear Hassan Labay:

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" (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 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, Ph.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: K132369

Device Name: Hansen Medical Magellan Robotic System, Magellan Robotic Catheter 9Fr (Formerly known as NorthStar Robotic Catheter)

Indications for Use:

Magellan Robotic System: The Hansen Medical Magellan Robotic System and accessory components are intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

The Magellan Robotic System is intended to be used with compatible Hansen Medical robotically steerable catheters.

Magellan Robotic Catheter 9Fr: The Hansen Medical Magellan Robotic Catheter 9Fr is intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

The Magellan Robotic Catheter 9Fr is intended to be used with the Hansen Medical Magellan Robotic System and accessories.

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)

Digitally signed by Owen P. Faris -S
Date: 2013.09.27 12:59:31 -04'00'