DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 27, 2015

Hansen Medical, Inc.
Kate Whitin Lee
Senior Director, Regulatory Affairs
800 East Middlefield Road
Mountain View, CA 94043

Re: K133552
Trade/Device Name: Hansen Magellan Robotic Catheter 6Fr
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: January 8, 2014
Received: January 9, 2014

Dear Ms. Lee:

This letter corrects the 510(k) Summary associated with our substantially equivalent letter of February 7, 2014.

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" (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 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,

for

Bram D. Zuckerman
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): K133552

Device Name: Hansen Medical Magellan Robotic Catheter 6Fr

Indications for Use:

The Hansen Medical Magellan Robotic Catheter 6Fr 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 6Fr 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)

Kenneth J. Cavanaugh -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: **K133552**

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:	Kate Whitin Lee
Phone Number:	650 404 5841
Facsimile Number:	650 404 2773
Date Prepared:	November 18, 2013

Device Information:

Regulatory Class:	Class II
Trade/Device Name:	Hansen Medical Magellan Robotic Catheter 6Fr
Common name:	Robotic Control Catheter
Classification name:	Steerable catheter
Regulation number:	21 CFR 870.1280
Product Code:	DRA

Predicate Device:

The Hansen Medical Magellan Robotic Catheter 6Fr is substantially equivalent in intended use and method of operation to the Hansen Medical Magellan Robotic Catheter 9Fr (K132369).

Device Description:

The Magellan Robotic Catheter 6Fr (MRC 6Fr) and accessories are a modification of the predicate Magellan Robotic Catheter 9Fr (MRC 9Fr) and accessories cleared under K132369. The Magellan Robotic Catheter 6Fr is a smaller size catheter comprised of a Guide (Outer Catheter) with dual bend articulating sections (distal and proximal) paired with a non-articulating Leader (Inner Catheter). The device is provided in two lengths (60cm and 95cm). Like the predicate device, the MRC 6Fr is designed to be used with Hansen Medical Magellan Robotic System and is intended to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices. The MRC 6Fr may also be used for delivery of diagnostic contrast agents. The device is provided sterile and is intended for single use only. The catheter is designed to expand Hansen Medical's market offering of compatible devices available for use with the Magellan Robotic System cleared under K132369.

Indications for Use:

The Hansen Medical Magellan Robotic Catheter 6Fr 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 6Fr is intended to be used with the Hansen Medical Magellan Robotic Catheter System and accessories.

Comparison to Predicate Device(s):

The Magellan Robotic Catheter 6Fr is smaller in outer diameter than the predicate device MRC 9Fr. The modified device combines the functionality of the articulating sections of the MRC 9Fr Inner and Outer Catheters (Leader and Guide catheters) into a dual bend steerable Guide with a Wire Support that may be used with a non-articulating Leader. 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 Magellan Robotic Catheter 6Fr is substantially equivalent to the predicate device in intended use, fundamental scientific technology, and performance specifications. Design verification testing was performed to verify that the performance of the Magellan Robotic Catheter 6Fr remains substantially equivalent to the predicate device. The catheter has been tested for biocompatibility according to ISO10993-1 and was determined to be

biocompatible. Testing performed on the Magellan Robotic Catheter included the following:

- Visual and Dimensional Verification Testing
- Pressure Leak Testing
- Vacuum Testing
- Tensile Strength Testing
- Flush Testing
- Articulation/Bending Stiffness Testing
- Fatigue Testing
- Guide wire Testing
- Simulated Use Testing
- Biocompatibility Testing
  - ISO MEM Elution Cytotoxicity Test
  - ISO Kligman Maximization Test
  - ISO Intracutaneous Reactivity Study
  - ISO Acute Systemic Toxicity Study
  - ASTM Hemolysis
  - ISO Thrombogenicity Study
  - Prothrombin Time (PT) Assay - ISO
  - ISO Complement Activation Assay

All of the pre-determined acceptance criteria were met.

Clinical Testing:

Clinical evaluation is not required for this device.

Substantial Equivalence:

The Magellan Robotic Catheter 6Fr has the following similarities to the Magellan Robotic Catheter 9Fr predicate device cleared under K132369.

- has the same indication for use,
- has the same fundamental scientific technology,
- has the same technological characteristics,
- has the same principles of operation,
- incorporate the same basic catheter design, and
- has the same sterilization process.
- has the same shelf life

Summary:

In summary, the Magellan Robotic Catheter 6Fr and accessory components subject to this submission are as safe and effective as the Magellan Robotic Catheter 9Fr and accessory components. It has the same indication for use, the same technological characteristics, and the same principles of operation as the Magellan Robotic Catheter 9Fr. The differences between the Magellan Robotic Catheter 6Fr and the Magellan Robotic Catheter 9Fr raise no new issues of safety or effectiveness. Performance data demonstrate that the Magellan Robotic Catheter 6Fr and accessory components are as safe and effective as the Magellan Robotic Catheter 9Fr and accessory components and is therefore substantially equivalent to the predicate device.