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.
Elisa Aldridge
Staff Regulatory Affairs Associate
800 East Middlefield Road
Mountain View, CA 94043

Re: K151463
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: July 22, 2015
Received: July 23, 2015

Dear Ms. Aldridge:

This letter corrects the 510(k) Summary associated with our substantially equivalent letter of August 18, 2015.

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,

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): To be determined

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)

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: **K151463**

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:	Elisa Aldridge
Phone Number:	650 404 2784
Facsimile Number:	650 404 2773
Date Prepared:	May 29, 2015

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 v1.2 is substantially equivalent in intended use and method of operation to the Hansen Medical Magellan Robotic Catheter 6Fr (K133552).

Device Description:

The Magellan Robotic Catheter 6Fr v1.2 and accessories are a modification of the predicate Magellan Robotic Catheter 6Fr (MRC 6Fr) and accessories cleared under K133552. Both the predicate device and the modified Magellan Robotic Catheter 6Fr are comprised of a Guide (Outer Catheter) with dual bend articulating sections (distal and proximal) paired with a non-articulating Leader (Inner Catheter). The devices are provided in two lengths (60cm and 95cm). Like the predicate device, the MRC 6Fr v1.2 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. Both the MRC 6Fr v1.2 and the predicate may also be used for delivery of diagnostic contrast agents. The modified MRC 6Fr is compatible with power contrast injection systems up to a maximum of 600 psi. Whereas, the predicate device is rated for a maximum pressure of 100 psi. The device is provided sterile and is intended for single use only. The catheter is one of several compatible devices available for use with Hansen Medical's Magellan Robotic System cleared under K111004, K132369 and K141614.

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 v1.2 is a modification of the predicate device to allow for compatibility with power contrast injection systems of the Magellan Robotic Catheter 6Fr Guide to pressures up to a maximum of 600 psi. The catheter modifications involve replacement of the predicate device Guide flush line and stopcock with a high pressure braided flush line and female luer connector. The changes are limited to the flush line. The main body of the catheter and the splayer remain unchanged. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device. This modified catheter will also be marketed under the name Magellan Robotic Catheter 6Fr.

Technological Characteristics/Performance Data:

The Magellan Robotic Catheter 6Fr v1.2 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 v1.2 remains substantially equivalent to the predicate device. Testing performed on the Magellan Robotic Catheter 6Fr v1.2 included the following:

- Pressure Burst Testing
- Pressure Leak Testing
- Tensile Strength Testing
- Simulated Use Testing
- Biocompatibility Testing
  - ISO MEM Elution Cytotoxicity Testing
  - ASTM Hemolysis
  - Chemical Characterization Testing

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 v1.2 has the following similarities to the Magellan Robotic Catheter 6Fr predicate device cleared under K133552.

- 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
- has the same sterilization process, and
- has the same shelf life.

Summary:

In summary, the Magellan Robotic Catheter 6Fr v1.2 and accessory components subject to this submission are as safe and effective as the Magellan Robotic Catheter 6Fr 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 6Fr. The differences between the modified Magellan Robotic Catheter 6Fr and the Magellan Robotic Catheter 6Fr raise no new issues of safety or effectiveness. Performance data demonstrate that the modified Magellan Robotic Catheter 6Fr v1.2 and accessory components are as safe and effective as the Magellan Robotic Catheter 6Fr and accessory components and is therefore substantially equivalent to the predicate device.