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 20, 2016

Hansen Medical, Inc.
Joy Sacmar
VP, QA & RA
800 E Middlefield Road
Mountain View, California 94043

Re: K160919
Trade/Device Name: Hansen Medical Magellan Robotic Catheter 9Fr
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: August 15, 2016
Received: August 16, 2016

Dear Joy Sacmar:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160919

Device Name
Hansen Medical Magellan™ Robotic Catheter 9Fr

Indications for Use *(Describe)*
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 Long Length (80 cm) is also indicated for use as a conduit for manual placement of therapeutic devices in the neuro vasculature.

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5.0 510(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 **K160919**

Applicant Information

Owner Name:	Hansen Medical, Inc.
Address:	800 East Middlefield Road
	Mountain View, CA. 94043
Office Phone:	650-404-5800
Establishment Registration Number:	3006026430
Contact Person:	Marysa Loustalot
Company Contact:	Joy M. Sacmar, Vice-President RA/QA
Phone Number:	650 404 2777
Facsimile Number:	650 404 5901
Date Prepared:	September 13, 2016

Device Information

Regulatory Class:	Class II
Trade/Device Name:	Hansen Medical Magellan Robotic Catheter 9Fr
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 9Fr is substantially equivalent in intended use and method of operation to the MicroVention Chaperon 6Fr Guiding Catheter (K082385).

Reference Device

The Hansen Medical Magellan Robotic Catheter 9Fr (K132369).

Device Description

The proposed change to the Hansen Medical Magellan™ Robotic Catheter (MRC) 9Fr is to the Indications for Use only; there is no change to the fit, form, or function of the device or to any of its components and accessories cleared under K132369.

The MRC 9Fr is a telescoping design comprised of a steerable Leader within a steerable Guide and is designed to be used with the Hansen Medical Magellan™ Robotic System (Magellan System). The distal sections of each Hansen Catheter component articulate individually and the distal end of the Leader can extend up to 21cm beyond the distal end of the Guide.

The Leader is a tubular catheter with four pull wires articulating the distal 3cm. The Leader has a 6Fr outer diameter and 3Fr inner diameter, and is available in 125cm, 141cm, and 158cm lengths. The Leader fits inside the Guide and is only used in conjunction with the Guide. The distal end of the Leader has a 3cm flexible articulating section. The Leader has a radiopaque marker band between the articulating section and the atraumatic tip. The tip extends 4mm distal to the marker band.

The Guide is a tubular catheter with four pull wires articulating the distal 2.8cm. The Guide has a 6Fr inner diameter and 9Fr outer diameter. The Guide is available in 50cm, 65cm, or 80cm lengths. The Guide fits around the Leader and may be used with or without the Leader. When the Leader is removed from the Guide, a 6Fr compatible percutaneous catheter may be delivered through the Guide.

Figure 5-1 below is a diagram taken from the current commercially available MRC 9Fr Guide (80cm) Box Label providing additional details on tip dimensions.

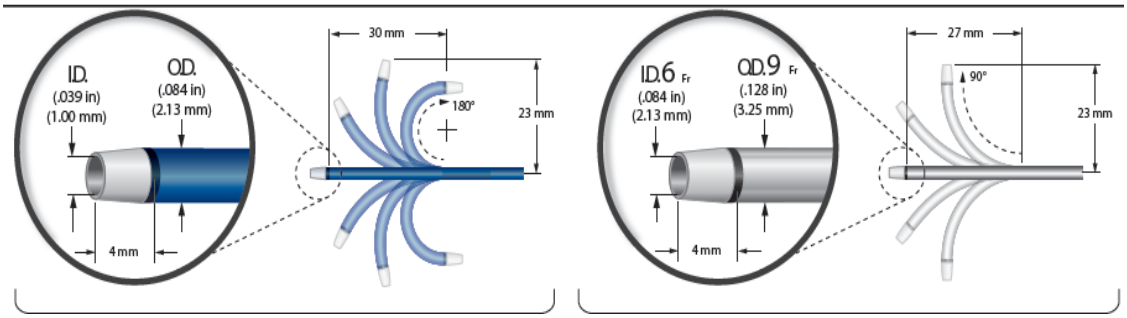

Figure 5-1 MRC 9Fr diagram taken from label PN 20995 Rev. C

The Hansen Catheter family consists of three different lengths of Leader and Guide pairs, and all sizes are sterilized via EtO for single use only. However, the MRC 9Fr Short (50cm) and MRC 9Fr Medium (65cm) catheters are not included for the expanded indication as they are not long enough to access the target anatomy. **Table 5-1** below lists all sizes the MRC 9Fr is currently available in.

Table 5-1 Magellan™ Robotic Catheter 9Fr - Lengths

Catalog Number	1. Guide Effective Length (cm)	2. Guide Overall Length (cm)	3. Leader Overall Length (cm)	Total Effective Length (cm)	Minimum Guide Wire Length for Exchange (cm)
MC9F50 (11142)	50	74	125	71	260
MC9F65 (11141)	65	90	141	86	260
MC9F80 (11140)	80	107	158	101	300

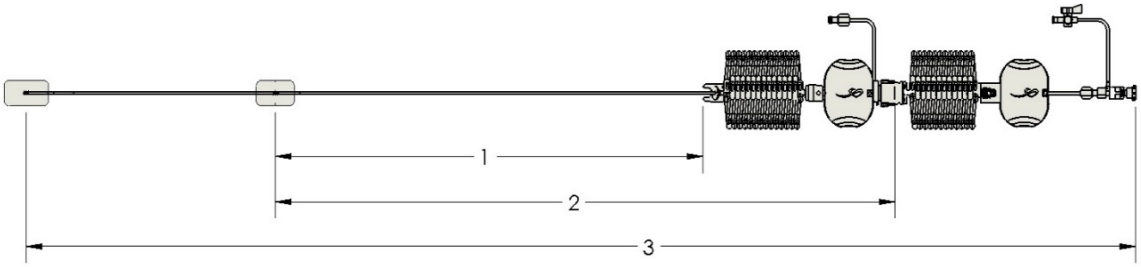

Figure 5-2 Magellan™ Robotic Catheter 9Fr

Intended Use

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 Long Length (80 cm) is also indicated for use as a conduit for manual placement of therapeutic devices in the neuro vasculature.

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

Comparison to Predicate Device(s)

The Hansen Medical Magellan Robotic (MRC) 9Fr Long Length (80cm) Guide and Leader is substantially equivalent to the MicroVention 6Fr Chaperon Guiding Catheter System.

The MRC 9Fr remains as a telescoping design, comprised of a steerable Leader within a steerable Guide and is designed to be used with the Hansen Medical Magellan™ Robotic System (Magellan System). The distal sections of each Hansen Catheter component articulate individually, and the distal end of the Leader can extend up to 21 cm beyond the distal end of the Guide. The MRC 9Fr Long Length is the only size available in the MRC 9Fr family that can access the neurovasculature at a total insertion length (Guide and Leader Catheter) of 101 cm.

Technological Characteristics/Performance Data

The MicroVention 6Fr Chaperon Guide catheter was chosen as the predicate device as it has a similar intended use and target anatomy as the MRC 9Fr Long Length (80cm) expanded indication. The Chaperon and Magellan catheters are both access catheters intended to provide a conduit for manual delivery of therapy. Diameters, lengths, and tip shape are the critical characteristics that determine the performance ability of an access catheter.

The MRC 9Fr Long Length (80cm) with the expanded indication and the predicate MRC 9Fr device cleared under K132369 have the same technological characteristics. In comparison to the MicroVention 6Fr Chaperon guide and inner catheters (the predicate device), the MRC 9Fr Long Length (8cm) has similar characteristics that determine the performance of accessing the neuro vasculature. The minor differences in the characteristics between the two products do not alter the performance and do not present any new issues of safety or effectiveness. Performance of the MRC 9Fr

Long Length (80cm) to access the neuro vasculature was further demonstrated in the design validation and verification activities described in Section 18.0 Performance Testing.

Therefore, the Hansen Medical Magellan Robotic 9Fr Long Length (80cm) is substantially equivalent with respect to intended use and technological characteristics as the predicate device, and is expected to perform equivalently in accessing the neuro vasculature.

Clinical Testing

Clinical evaluation is not required for this device.

Substantial Equivalence

Product	**MicroVention Inc. 6 Fr Chaperon Guiding Catheter System**	**Hansen Medical Magellan Robotic Catheter 9Fr w/ Expanded Indication**
Code Class 21CFR K Number	DQY (Percuraneous Catheter) Class II 870.1250 K082385	DRA (Steerable Catheter) Class II 870.1280 K160919
Indications for Use	Chaperon Guiding Catheter is intended for general intravascular use, including the neuro and peripheral vasculature. Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. Chaperon Guiding Catheter is not intended for use in coronary arteries.	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 Long Length (80 cm) is also indicated for use in the U.S. as a conduit for manual placement of therapeutic devices in the neuro vasculature. The Magellan™ Robotic Catheter 9Fr is intended to be used with the Hansen Medical Magellan™ Robotic System and accessories.

Performance Attribute and Characteristic Comparison of the Hansen Medical MRC 9Fr and the MicroVention Chaperon 6Fr

Performance Specification	MRC 9Fr Guide (Long)	Chaperon Guide	MRC 9Fr Leader	Chaperon Leader	Rationale Section
OD	9Fr 0.128 in	6F 0.084 in	6Fr 0.084 in	5F 0.071 in	12.3.3.1
ID	6Fr 0.084 in	5Fr 0.071 in	3Fr 0.039 in	3Fr 0.048 in	12.3.3.2
Guidewire Compatibility	0.035 in 0.018 in 0.014 in	0.035 in	0.035 in 0.018 in 0.014 in	0.035 in	12.3.3.3
Total Insertion Length	80 cm	95 cm	101 cm	117 cm	12.3.3.4
Distal Flex Length	2.7 cm	7 cm	3.0 cm	7 cm	12.3.3.5
Hydrophilic Coating Length	45 cm	N/A	85 cm	15 cm	12.3.3.6
Tip Configuration	Configurable bend to any angle up to 90° in all directions	STR, MP2, BUR	Configurable bend to any angle up to 180° in all directions	VTR, SIM2, JB2	12.3.3.7

Conclusion

In comparison to the MicroVention 6Fr Chaperon guide and inner catheters (the predicate device), the MRC 9Fr Long Length (8cm) has similar characteristics that determine the performance of accessing the neuro vasculature. The minor differences in the characteristics between the two products do not alter the performance and do not present any new issues of safety or effectiveness.

Therefore, the Hansen Medical Magellan Robotic 9Fr Long Length (80cm) is substantially equivalent with respect to intended use and technological characteristics as the predicate device, and is expected to perform equivalently in accessing the neuro vasculature as the predicate device.