



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

February 1, 2016

Hansen Medical, Inc.
Marysa Loustalot
Sr. Regulatory Affairs Associate
800 E Middlefield Road
Mountain View, CA 94043

Re: K153304

Trade/Device Name: Hansen Medical Magellan Robotic Catheter eKit
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: January 15, 2016
Received: January 19, 2016

Dear Marysa Loustalot:

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

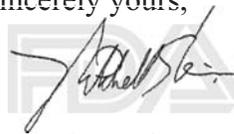
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, large watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153304

Device Name

Hansen Medical Magellan Robotic Catheter eKit

Indications for Use (Describe)

The Hansen Medical Magellan™ Robotic Catheter eKit 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 eKit 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.

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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 K153304

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
Phone Number: 650 404 5824
Facsimile Number: 650 404 5901
Date Prepared: November 13, 2015

Device Information

Regulatory Class: Class II
Trade/Device Name: Hansen Medical Magellan Robotic Catheter eKit
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 eKit is substantially equivalent in intended use and method of operation to the Hansen Medical Magellan Robotic Catheter 6Fr (K151463).

Device Description

The Hansen Medical Magellan™ Robotic Catheter eKit (MRC eKit) incorporates Microcatheter Driver components to be used in conjunction with the Magellan Robotic Catheter 6Fr (MRC 6Fr) cleared under K515463. Both the predicate device (MRC 6Fr) and the MRC eKit are comprised of a Guide (Outer Catheter) with dual bend articulating sections (distal and proximal) paired with a non-articulating Leader. The devices are both provided in two lengths (60cm and 95cm) and have been designed to be used with Hansen Medical Magellan Robotic System. Both the MRC 6Fr and the MRC eKit are intended to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

The MRC eKit is comprised of the Hansen Medical 6Fr Guide catheter that is found in the commercialized product MRC 6Fr, and Microcatheter Driver components. The Microcatheter Driver components include a Microcatheter Support, a Microcatheter Driver base, a Connector Tube, a Support Tube packaged with and for use with the Leader, and a Microcatheter Valve. These components function the same as the Wire Support in the MRC 6Fr device to robotically insert and retract the Leader. Modifications have been made to now allow for robotic insertion and retraction of third-party inner catheters / microcatheters compatible with 5F Guiding catheters (< 0.056" OD). There are no new materials or colorants used in the design of the Microcatheter Driver components. The main body of the catheter and the splayed remain unchanged. The optional proprietary non-articulating MRC 6Fr Leader (4.2 Fr OD x 3 Fr ID) is also available for use with the MRC eKit. The MRC 6Fr & eKit Leader is the same MRC 6Fr Leader cleared under K515463; only now it will be packaged with a Support Tube for use with the microcatheter driver.

Identical to the MRC 6Fr, the MRC eKit is provided sterile and is intended for single use only. The eKit is one of several compatible devices available for use with Hansen Medical's Magellan Robotic System (cleared under K111004, K132369, K141614, and K151730).

Figure 5.1 below is an illustration of the MRC eKit with a larger depiction of the new microcatheter driver components presented in **Figure 5.2**.

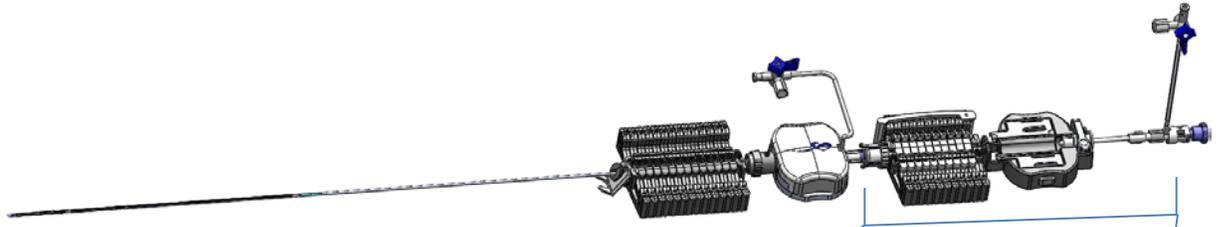


Figure 5.1 Magellan™ Robotic Catheter eKit (MRC eKit)

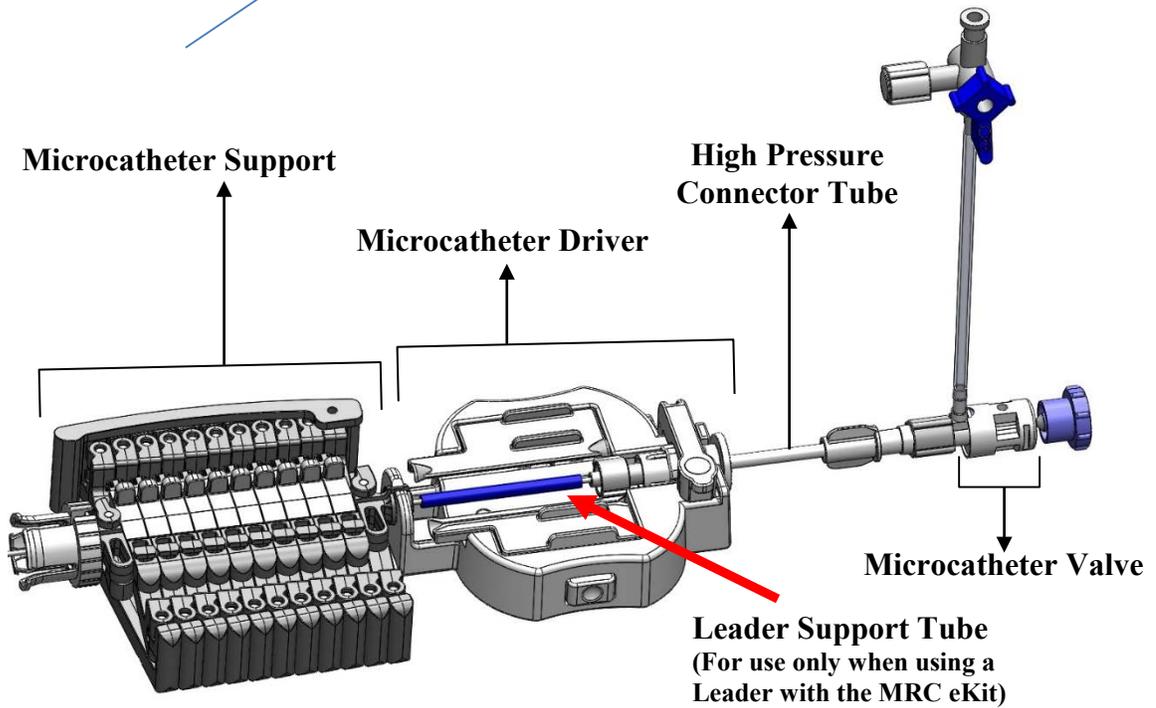


Figure 5.2 MRC eKit Microcatheter Components

Intended Use

The Hansen Medical Magellan™ Robotic Catheter eKit (MRC eKit) 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 eKit is intended to be used with the Hansen Medical Magellan™ Robotic System and accessories.

Comparison to Predicate Device(s)

The MRC eKit has the same intended use and the same fundamental scientific technology as its predicate device, the Magellan Robotic Catheter 6Fr.

Similar to the Wire Support on the MRC 6Fr, the MRC eKit comes with a Microcatheter Driver (MCD), an anti-buckling mechanism (MCD Support), a high pressure connector tube, and a leader valve assembly that allows for robotic insertion and retraction of a compatible third-party microcatheter or the Hansen MRC 6Fr Leader. A support tube is also included to prevent buckling within the base of the MCD when using the Leader only. The main body of the catheter and the splayer remain unchanged.

Per EN ISO 10993-1:2009, the MRC eKit finished device and components are categorized according to the nature and duration of body contact as an external communicating device with both indirect blood path contacting and direct circulating blood contact, with limited contact duration (< 24hr). There are no new materials in the MRC eKit, the MRC eKit Accessory Kit, or the MRC 6Fr & eKit Leader that are blood contacting. The material that is Blood Path, Indirect contacting has been previously tested and used in other Hansen Medical approved devices.

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 be marketed under the name the Magellan™ Robotic Catheter eKit.

Technological Characteristics/Performance Data

The MRC eKit is substantially equivalent to the predicate device in its intended use, fundamental scientific technology, and performance specifications. Design verification testing was performed to confirm that the performance of the MRC eKit remains substantially equivalent to the predicate device, as well as the reliability of inserting and retracting a third party microcatheter. Testing performed on the Microcatheter Driver components included the following:

- Dimensional Analysis
- Burst Pressure Testing
- Joint Separation Force Testing
- Simulated Use Testing

All of the pre-determined acceptance criteria were met.

Clinical Testing

Clinical evaluation is not required for this device.

Substantial Equivalence

The MRC eKit has the following similarities to the Magellan Robotic Catheter 6Fr predicate device cleared under K515463:

- the same intended use,
- the same fundamental scientific technology,
- the same principles of operation,
- the same basic catheter design,
- the same sterilization process, and
- the same shelf life.
- similar technological characteristics with minor modifications that do not impact the safety of efficacy of the device or its' intended use,

Conclusion

In summary, the Magellan Robotic Catheter eKit (MRC eKit) is as safe and effective as the predicate device, the Magellan Robotic Catheter 6Fr (MRC 6Fr) cleared under K151463. The differences between the MRC eKit and the MRC 6Fr raise no new issues of safety or effectiveness. Performance data demonstrate that the MRC eKit is as safe and effective as the Magellan Robotic Catheter 6Fr, and is therefore substantially equivalent to the predicate device.