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

March 9, 2016

Micro Medical Solutions, Inc.
Mr. Gregory Mathison
Vice President, Regulatory, Clinical & Quality
790 Willard Street, #209
Quincy, MA 02169

Re: K152625
Trade/Device Name: MMS Guide Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 29, 2016
Received: February 3, 2016

Dear Mr. Mathison,

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,

Kenneth J. Cavanaugh -S

for

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 on last page.

510(k) Number *(if known)*
K152625

Device Name
MMS Guide Catheter

Indications for Use *(Describe)*
The MMS Guide Catheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the peripheral vasculature.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Applicant:	Micro Medical Solutions, Inc. 240 Andover Street Wilmington, MA 01887 Tel: 978.909.3045
Trade Name:	MMS Guide Catheter
Common Name:	Guide Catheter
Classification Name:	Catheter, continuous flush
21CFR Number:	870.1210
Device Classification:	Class II
Product Code:	KRA
Predicate Devices:	Marksman Catheter (K111490)
Contact	Greg Mathison VP Regulatory, Clinical & Quality
DATE:	March 1, 2016

Substantially Equivalent to:

The MMS Guide Catheter is equivalent in intended use, principal of operation and technological characteristics to the Marksman Catheter (K111490).

Description of the device subject to premarket notification

The MMS Guide Catheter is a small diameter tubular device. It is inserted into the vasculature using standard access techniques and advanced over a guidewire to the physician desired location. The MMS Guide Catheter can be used as a pathway for other

diagnostic or therapeutic devices to enter the vasculature. The distal end has a standard luer fitting.

Indications for Use

The MMS Guide Catheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the peripheral vasculature.

Materials

All materials used in the manufacture of the MMS Guide Catheter are suitable for this use and have been used in numerous previously cleared products. The MMS Guide Catheter materials were tested per ISO10993 and found to be biocompatible. Testing included the following:

- Cytotoxicity
- Sensitization
- Acute Systemic Toxicity
- Hemolysis Extract
- Hemolysis Direct Contact
- Pyrogen
- Complement Activation
- Canine Thrombogenicity

Animal Testing

Animal testing was conducted to assess the simulated clinical performance of the Guide Catheter. The product performed to specification.

Cadaver Experience

Cadaver testing was conducted using the vasculature below the knee to assess the simulated clinical use of the product. The product performed to specification.

Non-Clinical Testing

Product testing was completed and met all of the acceptance criteria. Testing was conducted on sterile final product. Testing was performed on baseline (non-aged) and aged products. Testing included:

- Dimensional verification
- Surface Review
- Leak
- Tracking
- Flow
- Flex/Kink
- Torque
- Tensile
- Packaging

Performance Data

All necessary verification and validation testing has been performed for the MMS Guide Catheter to assure substantial equivalence to the predicate devices.

Basis for Determination of Substantial Equivalence

Upon reviewing the safety information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the MMS Guide Catheter is determined to be substantially equivalent to existing legally marketed devices.

Comparison of Product Features

Trade name	MMS Guide Catheter	Marksman Catheter	SE Discussion
Product code	KRA	KRA	Same product code
510(k) number	K152625	K111490	
21CFR	870.1210	870.1210	Same CFR number
Device Classification	II	II	Same – Class II
Device description	The MMS Guide Catheter is a small diameter tubular device. It is inserted into the vasculature using standard access techniques and advanced over a guidewire to the physician desired location. The MMS Guide Catheter can be used as a pathway for other diagnostic or therapeutic devices to enter the vasculature. The distal end has a standard luer fitting.	The Marksman Catheter is a variable stiffness, single lumen catheter designed to access small, tortuous vascular areas. The outer surface of the catheter's distal segment is coated with a hydrophilic material to provide lubricity during use. The catheter also incorporates a PTFE liner to facilitate movement of introduction devices passed through its lumen. The Marksman Catheter has a radiopaque marker at the distal tip to facilitate fluoroscopic visualization. The distal tip of the catheter is shapeable. The Marksman Catheter is provided with various working lengths. The Marksman Catheter is for single use only.	The device description is the same.

Intended Use	The MMS Guide Catheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the peripheral vasculature.	The Marksman Catheter is indicated for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral and coronary vasculature.	Same Indications for Use
Length	40 cm working length	105cm	Equivalent
Diameter	3.2 Fr	0.027”	Equivalent
Method of visualization	Fluoro / Ultrasound	Fluoro	Equivalent
Sterilization	Yes - ETO	Yes - ETO	Both devices are supplied sterile.
Single use	Y	Y	Same
Shelf life	22 months after production	Not indicated on submission	This will be on the product label
Packaging	Tyvek / Poly pouch	Unknown	Tyvek / Poly heat sealed pouches are common packaging for sterile products
Materials	Biocompatible	Biocompatible	Biocompatible

Conclusion

The products are substantially equivalent as the indications for use are the same, the clinical application is the same, the materials are equivalent, the dimensions are equivalent and the tested product performance attributes are equivalent.