



Food and Drug Administration  
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April 25, 2016

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

Re: K152934  
Trade/Device Name: MMS PTA Balloon Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: LIT  
Dated: February 29, 2016  
Received: March 17, 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

### Indications for Use

510(k) Number (if known)

K152934

Device Name

MMS PTA Balloon Catheter

Indications for Use (Describe)

The Micro Medical Solutions PTA Balloon Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including anterior tibial, posterior tibial, and pedal. Not for use in coronary arteries.

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.\***

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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  
240 Andover Street  
Wilmington, MA 01887  
Tel: 978.909.3045

Trade Name: MMS PTA Balloon Catheter

Common Name: Balloon Catheter

Classification Name: Catheter, continuous flush

21CFR Number: 870.1250

Device Classification: Class II

Product Code: LIT

Predicate Devices: Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter (K122940)

Contact: Greg Mathison  
VP Regulatory, Clinical & Quality

Date: March 1, 2016

### Substantially Equivalent to:

The MMS PTA Balloon Catheter is equivalent in intended use, principal of operation and technological characteristics to the Advance Micro 14 catheter (K122940).

## **Description of the device subject to premarket notification**

The Micro Medical Solutions PTA Balloon Catheter is a single lumen catheter with a balloon located at the distal tip. As the MMS PTA Balloon Catheter is not an Over-The-Wire device. The catheter consists of a single lumen for balloon inflation and deflation.. Inscribed on the proximal strain relief of the catheter is the balloon diameter (mm) and balloon length (mm). Platinum/Iridium marker bands are positioned on the shaft within the balloon to enable visualization of the catheter/balloon under fluoroscopy.

## **Indications for Use**

The Micro Medical Solutions PTA Balloon Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including anterior tibial, posterior tibial, and pedal. Not for use in coronary arteries.

## **Materials**

All materials used in the manufacture of the MMS PTA Balloon Catheter are suitable for this use and have been used in numerous previously cleared products. The MMS PTA Balloon 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
- Flex/Kink
- Torque
- Tensile
- Balloon fatigue
- Balloon burst
- Packaging
- Aging

### Performance Data

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

### Basis for Determination of Substantial Equivalence

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

### Comparison of Product Features

Trade name	MMS PTA Balloon Catheter	Advance Micro 14 Ultra Low-Profile PTA Balloon	SE Discussion
Product code	LIT	DQY	Equivalent
510(k) number	K152934	K122940	
21CFR	870.1250	870.1250	Same CFR number
Device Classification	II	II	Same – Class II
Device description	The Micro Medical Solutions PTA Balloon Catheter is a single lumen catheter with a balloon located at the distal tip. As the MMS PTA Balloon Catheter is not an Over-The-Wire device. The catheter consists of a single lumen for balloon inflation and deflation.. Inscribed on the proximal strain relief of	The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is an over-the-wire catheter available with an inflated balloon diameter of 1.5 mm with balloon lengths of 2 and 4 cm and balloon diameter of 2, 2.5, and 3 mm with balloon lengths of 2, 3, 4, 6,8, 10, and 12 cm. The catheter is 2.5 French in outer diameter with a length of 50, 90, or 150 cm. The catheter is	The device description is the same.

	<p>the catheter is the balloon diameter (mm) and balloon length (mm). Platinum/Iridium marker bands are positioned on the shaft within the balloon to enable visualization of the catheter/balloon under fluoroscopy.</p>	<p>compatible with a 0.014 inch (0. mm) diameter wire guide. It will be supplied sterile, intended for one time use.</p>	
Intended Use	<p>The Micro Medical Solutions PTA Balloon Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including anterior tibial, posterior tibial, and pedal. Not for use in coronary arteries.</p>	<p>The Advance Micro 14 Ultra Low-Profile PTA Balloon Catheter is intended for percutaneous transluminal angioplasty (PTA) of lesions in peripheral arteries including internal pudendal, iliac, renal; popliteal, femoral, iliofemoral, anterior tibia], posterior tibial, peroneal, pedlal, radial, brachial, and ulnar, as well as obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary arteries.</p>	Same Indications for Use
Catheter Length	65 cm working length	50cm, 90cm, and 150cm	
Catheter Diameter	3.2 Fr	3.2 Fr maximum	Equivalent
Balloon Diameters	2.0, 2.5, 4.0 F	2, 2.5, and 3 mm	Equivalent
Balloon length	20, 40 and 80mm	2, 3, 4, 6,8, 10, and 12 cm	Equivalent
Guidewire	Not over-the-wire Removable stylet	.014 compatible	Equivalent
Method of visualization	Fluoro / Ultrasound	Fluoro	Equivalent
Sterilization	Yes - ETO	Yes - ETO	Both devices are supplied sterile.
Single use	Yes	Yes	Same
Shelf life	12 months after production	Not indicated on submission	This will be on the product label

Packaging	Hoop sealed in a Tyvek / Poly pouch	Hoop sealed in a Tyvek / Poly pouch	Equivalent
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.