DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 8, 2017

Creagh Medical
% Ms. Shawn Fuller
Senior Director Clinical Affairs & Regulatory
Surmodics, Inc.
9924 West 74th Street
Eden Prairie, Minnesota 55344

Re: K171251
Trade/Device Name: 014 Hydrophilic Coated PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: August 9, 2017
Received: August 10, 2017

Dear Ms. Fuller:

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 (DICE) 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 (DICE) 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,

for Kenneth J. Cavanaugh -S

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)*
K171251

Device Name
014 Hydrophilic Coated PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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.

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5.0 510(k) SUMMARY AS REQUIRED BY 21CFR 807.92

510(k) Number: K171251

Date Prepared: April 27, 2017
Date Amended: August 9, 2017

Table 5.1 SUBMITTER INFORMATION

Submitter: Creagh Medical, Ltd., dba Surmodics, Inc. Street Address: IDA Business Park, Ballinasloe, Co. Galway, Ireland H53 K8P4 Establishment registration: 3005994106	Contact Person (U.S. Agent): Shawn Fuller Phone: 952-500-7090 Email: sfuller@surmodics.com Submitter: Shane Costello Regulatory Affairs Specialist Phone: 00 353 90 9646309 Email: scostello@surmodics.com

Table 5.2 DEVICE INFORMATION

Trade Name	014 Hydrophilic Coated PTA Balloon Dilatation Catheter
Common Name	PTA Balloon Dilatation Catheter
Classification Name	Catheter, Angioplasty, Peripheral, Transluminal
Regulation /Product Code	21 CFR 870.1250
Product Code	LIT
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is substantially equivalent to the previously-cleared WILLOW PTA Balloon Dilatation Catheter (K102645). The previously cleared AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheter (K050073, K052791, K042624, K083919) is also comparable to the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter in terms of technological characteristics and intended use, and will therefore be listed as a reference device for the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter.

Table 5.3 PREDICATE DEVICE

Predicate Device	**Manufacturer**	**FDA 510(k)**
WILLOW PTA Balloon Dilatation Catheter	Creagh Medical, Ltd.	K102645

Table 5.4 REFERENCE DEVICE

Reference Device	Manufacturer	FDA 510(k)
AMPHIRION DEEP 0.014” OTW PTA Balloon Dilatation Catheter	Medtronic, Inc	K050073, K052791, K042624, K083919

5.1 DEVICE DESCRIPTION

The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is an over the-wire (OTW) co-axial percutaneous transluminal angioplasty (PTA) catheter system designed for use with a 0.014" guidewire. The shaft of the PTA balloon catheter contains a distal balloon and a manifold on the proximal. The balloon has two radiopaque markers that aid in the placement of the balloon within the stenosis. The clearance between the inner and outer catheter shaft acts as the passage for the inflation medium for balloon expansion. The balloon and catheter shaft are coated with a hydrophilic coating.

The proximal end of the catheter has a bifurcated manifold and strain relief that allows for the use of the 0.014" guidewire and the attachment of a balloon inflation device via a standard luer connector. The inflation device is used to inflate and deflate the balloon with a contrast medium. The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is to be provided sterile (via ethylene oxide, EtO) and is intended for single use only.

5.2 INTENDED USE/INDICATIONS FOR USE (IFU)

The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

5.3 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter incorporates substantially equivalent device design, materials, packaging, manufacturing processes & sterilization method as the predicate WILLOW PTA Balloon Dilatation Catheter. The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter incorporates substantially equivalent device design, materials, and hydrophilic coating as the reference device, AMPHIRION DEEP 0.014” OTW PTA Balloon Dilatation Catheter. The 014 Hydrophilic Coated PTA Balloon Dilatation Catheter has the same indications for use and classification as both the predicate and reference devices. Where substantial equivalence is not directly demonstrated from the perspective of technology and

performance, design verification testing provides evidence of the substantial equivalence of the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter.

5.4 PERFORMANCE DATA

Testing has been performed to demonstrate substantial equivalence of the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter with the predicate device. The following non-clinical testing was performed:

- Bench Testing
- Biocompatibility
- Sterilization

Performance Bench Testing

The following performance bench testing was performed for the following design outputs:

- Rated Burst Pressure (RBP)
- Balloon Diameter at Nominal Pressure
- Multiple Inflation/Fatigue & Leak Test
- Balloon Length & Marker Band Position
- Inflation & Deflation Time
- Ancillary Tool Compatibility (Guidewire)
- Catheter Effective Length
- Tensile Strength (strength of the catheter shafts, bonds and tip)
- Device Compatibility (sheath, ancillary devices)
- Tip Profile (Geometry of the catheter most distal tip)
- Simulated Use
- Flexibility & Kink
- Coating Lubricity
- Particulate
- Radiopacity

The packaging system for the predicate WILLOW PTA Balloon Dilatation Catheter has been demonstrated to be equivalent to the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter, and the packaging validations for the predicate also support the packaging system for the WILLOW PTA Balloon Dilatation Catheter.

5.4.1 BIOCOMPATIBILITY

Biocompatibility of the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter has been evaluated in accordance with ISO 10993-1:2009, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and FDA Guidance “Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, Guidance for Industry and Food and Drug Administration Staff”. Per the requirements of ISO 10993-1 2009 the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is classified as an externally communicating device in contact with circulating blood for limited exposure duration. Biocompatibility tests appropriate for the device classification were selected, and testing was completed in accordance with FDA

Good Laboratory Practice (GLP) regulations (21 CFR, Part 58). The following biocompatibility tests were performed:

- Neutral Red Cytotoxicity Testing
- Kligman Maximization Sensitization Test
- Irritation by Intracutaneous Injection
- Acute Systemic Toxicity by Systemic Injection
- Rabbit Pyrogen Test (Material Mediated)
- Hemolysis ASTM Method (Direct and Indirect)
- C3a Complement Activation Assay
- SC5b Complement Activation Assay
- *In vivo* Thrombogenicity Assay

The results of the biocompatibility testing indicate that the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is biocompatible and suitable for its intended use.

5.4.2 STERILIZATION

The Ethylene Oxide (EtO) sterilization cycle used for the predicate device WILLOW has been adapted to include the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter. To confirm the suitability of the sterilization cycle for the device the following sterilization product testing has been completed:

- Product Bioburden (Bioburden Validation) – with the addition of the hydrophilic coating on the 014 Hydrophilic Coated Balloon Dilatation Catheter product bioburden impact needs to be considered.
- LAL/Endotoxin Testing (LAL Validation) – with the inclusion of the hydrophilic coating on the 014 Hydrophilic Coated Balloon Dilatation Catheter a new endotoxin validation will be required to be completed.
- Residual Degas Assessment – with the inclusion of the hydrophilic coating on the 014 Hydrophilic Coated Balloon Dilatation Catheter is there any change in the degas time required for the residual EO gas evaporate from the 014 Hydrophilic Coated Balloon Dilatation Catheter.

The results of the sterilization product testing have demonstrated that the Ethylene Oxide (EtO) sterilization method for the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter meets the requirements of ISO 11135:2014, and that the sterility of the device will be maintained.

Creagh Medical utilized the following sterilization site:
Synergy Health Ireland,
Sragh Industrial Estate,
Tullamore,
Co. Offaly,
Ireland.

5.4.3 CLINICAL DATA

No clinical data is being submitted for the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter.

5.5 CONCLUSIONS

Based upon the device description, indications for use, technological characteristics & performance data it can be concluded that the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter is substantially equivalent to the predicate device and is appropriate for the intended use.