April 19, 2018

Creagh Medical, Ltd.
% Ms. Sherri Mellingen
Senior Regulatory Affairs Specialist
Surmodics, Inc.
9924 West 74th Street
Eden Prairie, Minnesota 55344

Re: K180007
Trade/Device Name: 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: March 19, 2018
Received: March 20, 2018

Dear Ms. Mellingen:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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 below.

510(k) Number *(if known)*
K180007

Device Name
018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the peripheral vasculature in the iliac, 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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510(K) Summary

SURMODICS

Date Prepared: December 29, 2017

Submitters Name / Contact Person

510k Submitter Address		**Contact for Official/Routine Correspondence**
Shane Costello, Creagh Medical, Ltd., dba Surmodics, Inc. IDA Business Park, Ballinasloe, Co. Galway, H53 K8P4 Ireland **510k Submitter Establishment Registration Number** 3005994106		Sherri Mellingen, Senior Regulatory Affairs Associate, Surmodics, Phone – (952) 500 – 7081 Fax – (952) 500-7001 Email – smellingen@surmodics.com

General Information	
Trade Name:	018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter
Common / Usual Name:	PTA Balloon Dilatation Catheter
Classification Name	Catheter, Angioplasty, Peripheral, Transluminal
Regulation/Product Code	21 CFR 870.1250
Device Panel	Cardiovascular
Regulatory Classification:	Class II
Product Code:	LIT
Predicate Device:	Sterling™ Over-the-Wire™ (OTW) PTA Balloon Dilatation Catheter 510(k)#: K132430

Device Description

The catheter is a coaxial catheter with a semi compliant balloon near the distal tip. It is an Over-the-Wire (OTW) Percutaneous Transluminal Angioplasty (PTA) device with various shaft lengths. The balloon has two radiopaque markers that aid in the placement of the balloon within the stenosis. The clearance between the inner and outer shafts acts as the passage for the inflation medium for balloon expansion. The proximal end of the catheter has a bifurcated manifold & strain relief that allows for the use of the 0.018" 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 device is used by positioning the balloon catheter over a guidewire. The balloon is aligned under fluoroscopy in the diseased vessel at the area to be treated. The balloon is then inflated with inflation media to pressures ranging between the nominal and the rated burst pressure to dilate the occluded area. On completion the balloon is then deflated under vacuum and removed from the patient. The 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter is to be provided sterile (via ethylene oxide, EtO) and is intended for single use only.

Intended Use / Indications

The 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the peripheral vasculature in the iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Comparison of Technological Characteristics

The 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate device (Sterling Over-the-Wire (OTW) PTA Balloon Dilatation Catheter) device in design, intended use, principles of use, materials, sizes and sterility. The 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter and the predicate device are indicated for Percutaneous Transluminal Angioplasty (PTA) of peripheral vasculature stenoses in the iliac, femoral, ilio-femoral, infra-popliteal, popliteal, renal and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Both devices have similar device design, risk classification & product code. The devices are made from similar materials and both have a lubricious hydrophilic coating. 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 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter with the predicate device.

Substantial Equivalence and Summary of Studies

Testing has been performed to demonstrate substantial equivalence of the 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter to the predicate device. The following non-clinical testing was performed:

- Performance Bench Testing
- Biocompatibility
- Sterilization

Performance Bench Testing

Results of design verification testing demonstrate that the technological differences identified do not raise new questions of safety or effectiveness compared to the predicate device. The 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter has been evaluated through the following tests:

- 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

Biocompatibility

Biocompatibility of the 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter has been evaluated in accordance with ISO 10993-1, "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 the 018 Hydrophilic Coated OTW 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
- Thrombogenicity Testing

All test results met documented acceptance criteria and did not raise new questions of safety or effectiveness.

Sterilization

To confirm the suitability of the sterilization cycle for the device the following sterilization product testing has been completed:

- Sterilization Product Testing at the sub-lethal cycle and full cycle of the validated sterilization cycle.
- Product Bioburden (Bioburden Validation) – with the addition of the hydrophilic coating on the 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter product bioburden impact needs to be considered.

- LAL/Endotoxin Testing (LAL Validation) – with the inclusion of the hydrophilic coating on the 018 Hydrophilic Coated OTW PTA 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 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter is there any change in the degas time required for the residual EO gas evaporate from the 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter.

The results of the sterilization product testing have demonstrated that the Ethylene Oxide (EtO) sterilization method for the 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter meets the requirements of ISO 11135, 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.

Clinical Data
No clinical data is being submitted for the 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter.

Conclusions
Based upon the device description, indications for use, technological characteristics & performance data it can be concluded that the 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter is substantially equivalent to the predicate devices and is appropriate for the intended use.