May 14, 2020

Creagh Medical Ltd.
Amy Yanta
Regulatory Affairs
9924 W 74th St
Eden Prairie, MN 55344

Re: K200700
Trade/Device Name: Surmodics™ Sublime™ Radial Access 014 RX PTA (Percutaneous Transluminal Angioplasty) Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: March 16, 2020
Received: March 17, 2020

Dear Ms. Yanta:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200700

Device Name
Surmodics™ Sublime™ Radial Access 014 RX PTA (Percutaneous Transluminal Angioplasty) Dilatation Catheter

Indications for Use *(Describe)*
The Sublime™ Radial Access 014 RX PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenoses in the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, 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: March 16, 2020

Submitters Name / Contact Person

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510k Submitter Establishment Registration Number
3005994106

General Information	
Trade Name:	Surmodics™ Sublime™ Radial Access 014 RX PTA (Percutaneous Transluminal Angioplasty) Dilatation Catheter
Common / Usual Name:	014 RX PTA 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:	014 Hydrophilic Coated PTA Balloon Dilatation Catheter 510(k)#: K171251

Device Description

The 014 RX PTA Dilatation Catheter is a co-axial rapid exchange (RX) catheter system with a semi compliant balloon at the distal end designed for use with a 0.014" guidewire. The guidewire will pass through a lumen from an RX access bond. The balloon has two radiopaque markers that aid in the placement of the balloon within the stenosis. The balloon and catheter shaft are coated with a hydrophilic coating. The proximal end of the catheter has a single standard luer hub connector for connection of an inflation device. The inflation device is used to inflate and deflate the balloon with a contrast medium. The clearance between the inner and outer shafts acts as the passage for the inflation medium for balloon expansion. 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 014 RX PTA Dilatation Catheter is to be provided sterile (via ethylene oxide, EtO) and is intended for single use only.

Indications for Use
The Sublime™ Radial Access 014 RX PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenoses in the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Comparison of Technological Characteristics
The 014 RX PTA Dilatation Catheter incorporates substantially equivalent device design, materials, packaging, manufacturing processes & sterilization method as the predicate 014 Hydrophilic Coated PTA Balloon Dilatation Catheter. The 014 RX PTA Dilatation Catheter incorporates substantially equivalent device design, materials, and hydrophilic coating as the predicate 014 Hydrophilic Coated PTA Balloon Dilatation Catheter. The 014 RX PTA Dilatation Catheter has the same indications for use and classification as the predicate device. 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 RX PTA Dilatation Catheter with the 014 Hydrophilic Coated PTA Balloon Dilatation Catheter.

Substantial Equivalence and Summary of Studies
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 014 RX PTA Dilatation Catheter has been evaluated through the following tests:

- Rated burst pressure (RBP)
- Inflation & deflation time
- Balloon diameters at nominal pressure
- Simulated use – pushability & trackability
- Coating lubricity
- Coating durability
- Coating length
- Ancillary tool compatibility (guidewire)
- Tip profile
- Multiple inflation/fatigue & leak test
- Tensile strength
- Flexibility & kink
- Particulate
- Torque strength

Biocompatibility
Biocompatibility of the 014 RX PTA 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 014 RX PTA 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:

- MEM Elution Cytotoxicity Testing
- Kligman Maximization Sensitization Test
- Irritation by Intracutaneous Injection
- Acute Systemic Toxicity by Systemic Injection
- Rabbit Pyrogen Test (Material Mediated)
- Hemolysis ASTM Method
- SC5b Complement Activation Assay
- Thrombogenicity Testing

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

Sterilization

The Ethylene Oxide (EtO) sterilization cycle used for the predicate 014 Hydrophilic Coated PTA Balloon Dilatation Catheter device will be adapted to include the 014 RX PTA Dilatation Catheter. 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)
- LAL/Endotoxin Testing (LAL Validation)
- Residual Degas Assessment

The results of the sterilization product testing have demonstrated that the Ethylene Oxide (EtO) sterilization method for the 014 RX PTA 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 014 Rx PTA Balloon Catheter.

Conclusions

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