June 16, 2021

Creagh Medical Ltd. (a wholly owned subsidiary of Surmodics, Inc)
Holly Ramirez
Senior Principal Regulatory Affairs Specialist
IDA Business Park
Ballinasloe, Galway H53 HY09
Ireland

Re: K211044
Trade/Device Name: Sublime Radial Access 018 RX Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 14, 2021
Received: May 17, 2021

Dear Holly Ramirez:

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: 06/30/2023
See PRA Statement below.

510(k) Number: K211044

Device Name
Sublime™ Radial Access 018 RX Dilatation Catheter

Indications for Use *(Describe)*
The 018 Radial Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenosis 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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510(k) Summary

Date Prepared: 07 April 2021

510K Submitter and Contact for Routine Correspondence

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510k Submitter Establishment Registration Number

3005994106

General Information	
Trade Name:	Sublime™ Radial Access 018 Rx 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:	Sublime™ Radial Access 014 RX PTA Dilatation Catheter (K200700)
Reference Device	018 Hydrophilic Coated Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter (K180007)

Device Description

The 018 Radial Access Rx 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 0.018" 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 018 Radial Access Rx Dilatation Catheter is provided sterile via ethylene oxide and is intended for single use only.

Indication for Use

The 018 Radial Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenosis 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.

Comparison of Technological Characteristics

The Surmodics Sublime Radial Access 018 Percutaneous Transluminal Angioplasty (PTA) Dilatation Catheter device is substantially equivalent to the 014 Radial Access Rx Dilatation Catheter (K200700) in design, intended use, principles of use, biocompatibility, sterility, and labeling. Changes to the predicate device that have led to the submission of this new 510(k) are geometric and material in nature. All characteristics that were not identical to the predicate device were verified through performance bench testing and determined to be substantially equivalent.

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 Balloon 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
- Particulates
- Torque Strength

Clinical Studies and Testing

No clinical studies were required for the 018 Radial Access Rx Dilatation Catheter.

Conclusion

Based on the device description, materials, technological characteristics, and accompanying performance data it can be concluded that the device modifications made to the 018 Radial Access Rx Dilatation catheter are substantially equivalent to the predicate device and the device will continue to function per its intended use.