October 14, 2022

Surmodics Inc.
Holly Ramirez
Senior Staff Regulatory Affairs Specialist
7905 Golden Triangle Drive Suite 190
Eden Prairie, Minnesota 55344

Re: K221886
Trade/Device Name: Sublime Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY, KRA
Dated: June 28, 2022
Received: June 29, 2022

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 *(if known)*
K221886

Device Name
Sublime™ Microcatheter

Indications for Use *(Describe)*
The Sublime™ Microcatheter is intended to access the peripheral vasculature in order to facilitate the placement and/or the exchange of guidewires. The Sublime Microcatheter is also intended to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

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.

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K221886 510(K) Summary

SURMODICS

Date Prepared: 10/3/2022

Submitters Name / Contact Person

510k Submitter Address

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Table 1: General Information	
Trade Name:	**Sublime™ Microcatheter**
Common / Usual Name:	Microcatheter
Classification:	Class II
Product Code:	DQY, KRA
Predicate Device:	K160884 CXI Support Catheter (cleared November 22, 2016)
Reference Devices:	K173560 Telemark Microcatheter (cleared January 12, 2018) K211044 Sublime 018 Radial Access Rx Dilatation Catheter (cleared June 16, 2021)

Device Description

The Sublime Microcatheter is a sterile, single-use, disposable intravascular catheter with an atraumatic distal tip and a proximal hub with a luer fitting.

The Sublime Microcatheter is a single lumen support catheter, compatible with 014", 018", and 035" guide wire platforms and a 4F guide catheter. It has a working length of up to 200 cm, and both straight and angled tip configurations. The catheter has a stainless-steel braid supported construction with hydrophilic coating. The distal end of the catheter includes a radiopaque markerband to facilitate visualization under fluoroscopy.

Intended Use / Indications

The Sublime Microcatheter is intended to access the peripheral vasculature in order to facilitate the placement and/or the exchange of guidewires. The Sublime Microcatheter is also intended to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Comparison of Technological Characteristics

The Sublime™ Microcatheter is substantially equivalent to the legally marketed predicate device in design, intended use, principles of use, materials, and sterility. The Sublime Microcatheter and the predicate device are intended as support catheters to assist in the placement and/or exchange of guidewires. Both devices have equivalent performance and safety profiles, as evidenced through design verification and comparative testing. The devices are made from similar materials, and both have a lubricious coating.

Table 2: Predicate Device Comparison		
510(k) #	K221886	K160884
Intended Use / Indications	The Sublime Microcatheter is intended to access the peripheral vasculature in order to facilitate the placement and/or the exchange of guidewires. The Sublime Microcatheter is also intended to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.	The CXI™ Support Catheter is intended for use in small vessel or super selective anatomy for diagnostic and interventional procedures, including peripheral use.
Principles of Use	The Sublime Microcatheter is presented to a sterile field through aseptic presentation. The device is inserted over a guidewire into the vasculature and advanced, following the path of the guidewire. The microcatheter acts a rigid support for the guidewire for sections of the vasculature that may be difficult to cross due to excessive stenosis, or where lesions may be present. Once in the intended location in the vasculature, the microcatheter lumen may be used to exchange guidewires, or for injection of saline solutions and contrast media.	The Cook CXI Support Catheter is presented to a sterile field through aseptic presentation. The device is inserted over a guidewire into the vasculature and advanced, following the path of the guidewire. The microcatheter acts a rigid support for the guidewire for sections of the vasculature that may be difficult to cross due to excessive stenosis, or where lesions may be present. Once in the intended location in the vasculature, the microcatheter lumen may be used to exchange guidewires, or for injection of saline solutions and contrast media.
Dimensions	Distal ID (inches): 0.015, 0.019, 0.036 Shaft OD: 2.4Fr, 2.6Fr, 4.0Fr Catheter Effective Length (cm): 65-200	Distal ID (inches): 0.014, 0.018, 0.035 Shaft OD: 2.3Fr, 2.6Fr, 4.0Fr Catheter Effective Length (cm): 65-150
Tip Configurations	Straight and Angled Tip Profiles	Straight and Angled Tip Profiles
Materials	Dual layer Stainless Steel Braid with reflowed PEBAX Jacket	Stainless Steel Braid with reflowed PEBAX Jacket
Distal Coating	Hydrophilic Coating	Hydrophilic Coating
Ancillary Device Compatibility	014”, 018”, and 035” guide wire	014”, 018”, and 035” guide wire
	4F Guide Catheter	4F Guide Catheter
Sterilization	Ethylene Oxide	Ethylene Oxide
Single Use	Single Use	Single Use

Substantial Equivalence and Summary of Studies

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 Sublime Microcatheter is

substantially equivalent to the predicate device based on intended use/indications for use and technological characteristics. The subject device has been evaluated through the following tests:

- Flow Rate
- Dimensional Evaluations
- Radiopacity
- Tensile Strength
- Freedom from Leakage
- Hub/Luer connector compatibility
- Guidewire Movement
- Burst Testing
- Flexibility and Kink Resistance
- Track Force
- Torque Strength
- Hydrophilic Coating
- Particulate Testing
- Atraumatic Surfaces
- Simulated Use Testing
- Biocompatibility
    - Cytotoxicity
    - Hemocompatibility
    - Sensitization
    - Acute System Toxicity
    - Irritation/Reactivity
    - Pyrogenicity

All test results met documented acceptance criteria and did not raise new questions of safety or effectiveness. The Sublime Microcatheter is substantially equivalent to the predicate device.