January 12, 2018

Surmodics, Inc.
Sherri Mellingen
Senior Regulatory Associate
9924 W 74th St
Eden Prairie, Minnesota 55344

Re: K173560
Trade/Device Name: Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 16, 2017
Received: November 17, 2017

Dear Sherri 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,

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)*
K173560

Device Name
Microcatheter

Indications for Use *(Describe)*
The Surmodics Microcatheter is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures and can be used to exchange one guidewire for another. This microcatheter is also intended to assist in the delivery of contrast media into the coronary and peripheral vasculatures.

Do not use this microcatheter other than for use in the coronary and peripheral vasculatures.

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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510(K) Summary

SURMODICS

Date Prepared: 11/16/2017

Submitters Name / Contact Person

510k Submitter Address

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Contact for Official/Routine Correspondence

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General Information	
Trade Name:	Microcatheter
Common / Usual Name:	Microcatheter
Classification:	Class 2 per 21 CFR 870.1250
Product Code:	DQY – Catheter, Percutaneous
Predicate Device:	ASAHI Caravel (k152447)

Device Description

The Surmodics Microcatheter is a sterile, single use, percutaneous device intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculature. Additionally, the microcatheter can be used for contrast media injection.

The catheter is a single-lumen microcatheter with a 1.9 Fr distal outer diameter, a 2.6 Fr proximal outer diameter and is compatible with a 0.014" guidewire. The proximal end of the catheter shaft has a larger inner diameter, outer diameter and wall thickness and tapers to the distal end. The catheter is available in lengths of 135 cm and 150 cm in length to facilitate access to various target sites.

Intended Use / Indications

The Surmodics Microcatheter is intended to provide support to facilitate the placement of guidewires in the coronary and peripheral vasculatures and can be used to exchange one guidewire for another. This microcatheter is also intended to assist in the delivery of contrast media into the coronary and peripheral vasculatures.

Do not use this microcatheter other than for use in the coronary and peripheral vasculatures.

Comparison of Technological Characteristics

The Surmodics Microcatheter device is substantially similar to the legally marketed predicate device in design, intended use, principles of use, materials, sizes and sterility. The Surmodics Microcatheter and the predicate device are intended to access discrete regions of the coronary and peripheral vasculature to facilitate the placement of or exchange of guidewires or to deliver contrast media. Both devices have similar dimensions and similar accessory compatibility. The devices are made from similar materials and both have a lubricious coating.

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 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:

- Visual inspections
- Dimensional evaluations
- Radiopacity
- Tensile strength
- Freedom from liquid leakage
- Hub/Luer connector compatibility
- Simulated use
- High pressure injection
- Particulate
- Flow Rate
- Kink resistance
- Tracking forces
- Torque strength
- Torque transmission
- Hydrophilic coating testing
- Freedom from air leakage
- Push transmittance
- 3 point bend
- Coating Integrity
- Package Performance Testing

The following biocompatibility tests were performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Systemic toxicity (acute)
- Hemocompatibility
- Pyrogenicity

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