September 29, 2023

Surmodics. Inc.
Jodie Christe
Regulatory Affairs Associate II
9924 West 74th Street
Eden Prairie, Minnesota 55344

Re: K232647
Trade/Device Name: Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 30, 2023
Received: August 31, 2023

Dear Jodie Christe:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Samuel G. Raben -S

for Lydia Glaw
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)*
K232647

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date Prepared: August 30, 2023

Submitters Name/Contact Person

510(k) Submitter and Contact for Routine Correspondence

Jodie Christe
Regulatory Affairs Associate II
Surmodics, Inc.
9924 West 74th Street
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510(k) Submitter Establishment Registration Number

3001374820

General Information	
Trade Name:	Microcatheter
Common / Usual Name:	Microcatheter
Classification Name	Cardiovascular
Regulation/Product Code	21 CFR 870.5150
Device Panel	Cardiovascular
Regulatory Classification:	Class II
Product Code:	DQY
Predicate Device:	Microcatheter (K173560)

8.1 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 working lengths of 135 cm and 150 cm to facilitate access to various target sites.

8.2 Indication for Use

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.

8.3 Comparison of Technological Characteristics

The Surmodics Microcatheter device is substantially equivalent to the legally marketed predicate device in design, intended use, principles of operation, catheter 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 only change from the predicate device is a modified lubricous hydrophilic coating. The modified hydrophilic top coat formulation, known as Preside, was developed to provide better customer experience.

8.4 Performance Bench Testing

Results of design verification and biocompatibility testing demonstrates that the technological and material differences identified do not raise new questions of safety or effectiveness compared to the predicate device. The Surmodics Microcatheter has been evaluated through the following tests:

- Coating Integrity
- Particulate
- Track Force
- Simulated Use (part of track force testing)
- Pinch testing - lubricity
- Biocompatibility

8.5 Clinical Studies and Testing

No clinical studies were required for the Surmodics Microcatheter.

8.6 Conclusion

Based on the device description, materials, technological characteristics, and accompanying performance and biocompatibility data it can be concluded that the device modifications made to the Surmodics Microcatheter are substantially equivalent to the predicate device and the device will continue to function per its intended use.