March 22, 2023

Creagh Medical Ltd
Peter Bather
Sr. Regulatory Affairs Associate
IDA Business Park
Ballinasloe, Galway H53 K8P4
Ireland

Re: K230191
Trade/Device Name: Arise™ UHP Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: January 23, 2023
Received: January 24, 2023

Dear Peter Bather:

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.03.22 15:26:29 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
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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)*
K230191

Device Name
Arise™ UHP Dilatation Catheter

Indications for Use *(Describe)*
The UHP Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac 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: January 23, 2023

Submitters Name / Contact Person

510k Submitter Address

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General Information	
Trade Name:	Arise™ UHP 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:	ELM High Pressure Balloon Dilatation Catheter 510(k)#: K102645

Device Description

The Surmodics™ Arise™ UHP Dilatation Catheter is a coaxial Over the Wire (OTW) 0.035" PTA Balloon Dilatation Catheter with a distal inflatable balloon intended to be used for the treatment of peripheral arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The UHP Dilatation Catheter obtains a low compliance at high pressure over a large working range. The proximal portion of the catheter has a bifurcated manifold which includes a balloon lumen marked "BAL" and a guidewire lumen. Two radiopaque marker bands indicate the dilatating section of the balloon and aid in the balloon placement. The catheter is designed so that a specific balloon diameter can be reached depending on the balloon size and defined pressure.

Intended Use / Indications
The UHP Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Comparison of Technological Characteristics
The UHP Dilatation Catheter is equivalent to the legally marketed predicate device (ELM High Pressure Balloon Dilatation Catheter) in design, indications for use, principles of use, materials, sizes, and sterility. The UHP Dilatation Catheter and the predicate device are indicated for Percutaneous Transluminal Angioplasty (PTA) dilation of peripheral vasculature stenosis in the femoral, iliac and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Substantial Equivalence and Summary of Studies
The UHP Dilatation Catheter is substantially equivalent to the predicate devices based on the indications for use, technological characteristics, and principles of use. Results of successful design verification testing demonstrate that the technological differences identified do not raise new questions of safety or effectiveness for the UHP Dilation Catheter compared to the predicate device. All test results met documented acceptance criteria and/or included justification of values.

The subject device has been evaluated through the following categories of testing.

- Performance Bench Testing
- Biocompatibility
- Sterilization

Performance Bench Testing
The UHP Dilatation Catheter has been evaluated through the following tests:

- Rated Burst Pressure (RBP)
- Balloon Diameter at Nominal Pressure
- Inflation & Deflation Time
- Balloon Length & Marker Band Position
- Radiopacity
- Ancillary Tool Compatibility (Guidewire)
- Catheter Effective Length
- Tip Profile (Geometry of the catheter most distal tip)
- Simulated Use
- Crossing Profile
- Multiple Inflation/Fatigue & Leak Test
- Tensile Strength (strength of the catheter shafts, bonds, and tip)
- Flexibility & Kink

Biocompatibility
Biocompatibility of the Braided Balloon 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 Braided Balloon Catheter is

classified as an externally communicating device in contact with circulating blood for limited exposure duration. Biocompatibility and chemical characterisation 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 and chemical characterization tests were performed in accordance with ISO 10993-1:

- Cytotoxicity
- Irritation / Intracutaneous Reactivity
- Sensitization
- Acute Systemic Toxicity
- Pyrogenicity
- Hemocompatibility
    - Hemolysis ASTM Method (Direct and Indirect)
    - C3a Complement Activation Assay
    - SC5b Complement Activation Assay
    - In Vivo Thrombogenicity
- Genotoxicity
- Bacterial Reverse Mutation
- Chemical Characterization

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

Sterilization
The results of the sterilization product testing have demonstrated that the Ethylene Oxide (EtO) sterilization method for the UHP Dilatation Catheter meets the requirements of ISO 11135, and that the sterility of the device will be maintained over the entirety of shelf life.

Animal Testing
No animal testing data is being submitted for the UHP Dilatation Catheter.

Clinical Data
No clinical data is being submitted for the UHP Dilatation Catheter.

Conclusions
Based upon the device description, indications for use, technological characteristics & performance data it can be concluded that the UHP Dilatation Catheter is substantially equivalent to the predicate device.