November 15, 2024

Creagh Medical Ltd. dba Surmodics, Inc.
Anne-Marie Keenan
Senior Regulatory Affairs Specialist
IDA Business Park, Ballinasloe
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Ballinasloe, H53 K8P4
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Re: K242419
Trade/Device Name: Advance Serenity™ 18 Hydrophilic PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 19, 2024
Received: September 19, 2024

Dear Anne-Marie Keenan:

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.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.11.15 19:09:54 -05'00'

For

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242419

Device Name
Advance Serenity™ 18 Hydrophilic PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the peripheral vasculature in the iliac, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510k Summary

Date Prepared: November 14, 2024

Submitters Name/Contact Person

510K Submitter and Contact for Routine Correspondence

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510k Submitter Establishment Registration Number
3005994106

General Information	
Trade Name:	Advance Serenity™ 18 Hydrophilic PTA Balloon 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:	018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter (K180007)
Reference Device	Sterling™ Over-the-Wire (OTW) PTA Balloon Dilatation Catheter (K132430)

1.1 Device Description

The Advance Serenity™ 18 Hydrophilic PTA Balloon Dilatation Catheter is a coaxial catheter with a semi compliant balloon near the distal tip. It is an Over-the-Wire (OTW) Percutaneous Transluminal Angioplasty (PTA) device with various shaft lengths. The balloon has two radiopaque markers that aid in the placement of the balloon within the stenosis. The clearance between the inner and outer shafts acts as the passage for the inflation medium for balloon expansion. The proximal end of the catheter has a bifurcated manifold & strain relief that allows for the use of the 0.018" guidewire and the attachment of a balloon inflation device via a standard luer connector. The inflation device is used to inflate and deflate the balloon with a contrast medium. 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 Advance Serenity™ 18 Hydrophilic PTA Balloon Dilatation Catheter is to be provided sterile (via ethylene oxide, EtO) and is intended for single use only.

1.2 Indications for Use

The Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the peripheral vasculature in the iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

1.3 Comparison of Technological Characteristics

The subject Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter is substantially equivalent to the predicate 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter (K180007) 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 the expansion of the matrix of dilatation balloons available for peripheral balloon angioplasty. All characteristics that were not identical to the predicate device were verified through performance bench testing and determined to be substantially equivalent.

Characteristic	Subject Device: K242419 Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter	Predicate Device: K180007 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter	Comparison
Indications for Use	The Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the peripheral vasculature in the iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	The 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) of the peripheral vasculature in the iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	Identical
Principles of Operation	Inflation of semi-compliant balloon for dilatation		Identical
Guidewire Compatibility	018”		Identical
Catheter Shaft Length (cm)	40, 90, 120, 135	40, 90, 120, 135, 150	Identical (40, 90, 120, 135cm)
Sheath Compatibility	5Fr	4Fr , 5Fr	Identical (5Fr)
Catheter Shaft Outer Diameter (mm)	5Fr: ≤1.667	4Fr: ≤1.333 5Fr: ≤1.667	Identical (5Fr)
Balloon Length (mm)	220	15, 20, 40, 60, 80, 100, 120, 150, 220	Identical (220mm)
Balloon Diameters (mm)	5.0, 6.0 & 7.0	2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 8.0, 9.0, 10.0	Identical (5.0, 6.0 & 7.0mm)
Nominal Pressure	8 ATM	8 ATM	Identical
Rated Burst Pressure	14 & 16 ATM	10, 12, 14, 16 ATM	Identical (14 & 16 ATM)
Balloon Material	Semi-Compliant		Identical
Catheter Shaft Materials	Polymers, all materials are biocompatible		Substantially Equivalent

Characteristic	Subject Device: K242419 Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter	Predicate Device: K180007 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter	Comparison
Radiopaque Marker Bands	Two radiopaque marker bands		Identical
Coating Material	Hydrophilic Coating		Identical
Packaging Configuration	Same function and design		Identical
Sterilization Method	Ethylene Oxide		Identical
Biocompatibility	Externally communicating device in contact with circulating blood for limited exposure duration.		Substantially Equivalent
Single Use/ Reprocess	Single use only		Identical

1.4 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 device has been evaluated through the following tests:

- Rated burst pressure (RBP)
- Inflation & deflation time
- Balloon diameters at nominal pressure to RBP
- Simulated use – Pushability & Trackability & Sheath Compatibility
- Coating integrity (b)
- Multiple inflation/fatigue & leak test
- Tensile strength – Balloon to Shaft (proximal bond)
- Particulate

Performance Bench Tests have been leveraged from predicate device for the following:

- Balloon Length & Marker Band Position
- Radiopacity
- Ancillary Tool Compatibility (Guidewire)
- Catheter Effective Length
- Tensile Strength Manifold to Shaft (Manifold Bond)
- Tensile Strength (Distal / Tip Bond)
- Tip Profile (Geometry of the catheter most distal tip)
- Simulated Use, Push & Track
- Flexibility & Kink
- Coating Lubricity
- Coating Integrity (a)
- Torque Strength

1.5 Clinical Studies and Testing

No clinical studies were required for the Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter.

1.6 Conclusion

Based on the device description, materials, technological characteristics, and accompanying performance data, it can be concluded that the device modifications made to the Advance Serenity 18 Hydrophilic PTA Balloon Dilatation Catheter are substantially equivalent to the predicate device.