September 2, 2022

Silk Road Medical, Inc.
Denise Aycox
Senior Regulatory Affairs Specialist
1213 Innsbruck Drive
Sunnyvale, California 94089

Re: K221414
Trade/Device Name: ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: May 12, 2022
Received: May 16, 2022

Dear Denise Aycox:

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)*
K221414

Device Name
ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter

Indications for Use *(Describe)*
The ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter is intended for percutaneous transluminal angioplasty and post-dilatation of self-expanding stents in the carotid arteries.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary

[as required by 21 CFR 807.92.(c)]

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Silk Road Medical is providing the summary of Substantial Equivalence for the ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter.

1.1. Sponsor/Applicant

Silk Road Medical
1213 Innsbruck Drive
Sunnyvale, CA 94089

1.2. Sponsor Contact

Primary Contact	Alternate Contact
Denise Aycox Sr. Regulatory Affairs Specialist. Ph: 408-585-2156 Email: daycox@silkroadmed.com	Kym Rupp Manager, Regulatory Affairs (407) 756-0035 Email: krupp@silkroadmed.com

1.3. Date of Preparation of 510(k)Summary

May 12, 2022

1.4. Device Trade or Proprietary Name

Trade Name	ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter

1.5. Device Classification

Regulatory Class	II
Classification Panel	Cardiovascular
Classification Name	Percutaneous Catheter
Common Name	PTA balloon dilatation catheter
Classification Regulation	870.1250
Product Code	LIT

1.6. Predicate Device

Predicate Device		
510(k) Number/ Clearance Date	**Name of Device**	**Name of Manufacturer**
K071189 Cleared on May 16, 2007	AVIATOR PLUS PTA Balloon Dilatation Catheter	Cordis Europa, N.V Oosteinde 8 Roden, NL NI-9301 Lj

1.7. Predicate Comparison

Predicate Comparison			
Device Name	**Predicate Device** **AVIATOR PLUS**	**Subject Device** **ENROUTE Enflate**	**For any differences, justification of substantial equivalence**
510(k) No.	K071189	TBD	N/A
Classification	Class II	SAME	
Classification Regulation	870.1250	SAME	
Product Code	LIT	SAME	
Indication for Use	The Cordis AVIATOR PLUS PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilia-femoral, popliteal, infra popliteal, renal, and carotid arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device ·1s also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.	The ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter is intended for percutaneous transluminal angioplasty and post-dilatation of self-expanding stents in the carotid arteries.	Both products are intended for transluminal angioplasty and post-dilatation of self-expanding stents in the carotid arteries. The predicate, AVIATOR PLUS, has an expanded indication while the ENROUTE Enflate has a more limited indication particularly for use in the carotid arteries.
Balloon Characteristics			
Catheter Type	Rapid Exchange (RX)	SAME	
Shaft	RX Coaxial	SAME	

Construction			
Guidewire Compatibility	.014”	SAME	
Sheath Compatibility	4 or 5F (4F (up to 6mm), 5F for 7mm)	SAME (4F for 4-5.5 mm diameters, 5F for 6 mm diameter)	Both the subject and predicate are compatible with 4F or 5F sheaths depending on the balloon diameter.
Nominal Pressure	10 atm	8 atm	The Nominal pressure is similar to the predicate and is consistent with other PTA balloons.
Rated Burst Pressure	14 atm (for diameters up to 6mm), 12 atm for 7mm	14 atm	The RBP for both the subject and predicate are 14 atm for balloon diameters up to 6mm. The 12atm RBP is for a 7mm diameter which is not an offered diameter size for the subject
Contrast Infusion	No	SAME	
Coating	None	SAME	
Marker band #	2	SAME	
Balloon Material	Duralyn	Nylon	The ENROUTE Enflate Catheter is constructed of materials commonly used for semi-compliant PTA balloons.
Dimensions			
Catheter Working Length	142cm	75cm	The shorter working length was selected to accommodate the TCAR procedure. The product is designed to have direct access to the carotid artery rather than femoral artery access.
Catheter Shaft Outer Diameter	1.10mm	1.14mm	The OD of the catheter shaft is similar to the predicate and falls in-line with other cleared PTA catheters.
Balloon Length	15mm, 20mm, 30mm or 40mm	25mm or 35mm	These lengths are similar to other cleared PTA balloon catheters for use in the carotid arteries.
Balloon Diameter	4.0, 4.5, 5.0, 5.5, 6.0 or 7.0 mm at nominal pressure	4.0, 4.5, 5.0, 5.5, or 6.0 mm at nominal pressure	The diameter sizes are identical to the predicate with the exception of the 7.0mm size. These diameters are

			consistent with other cleared PTA balloon catheters for use in the carotid arteries.
Packaging and Sterilization			
Packaging Configuration	Balloon and flushing needle provided in Tyvek pouch. The balloon is packaged in a protective hoop.	Balloon packaged in a protective hoop in a Tyvek pouch	The Packaging configuration is identical to the predicate except a flushing needle is not included.
Sterilization Method	EO	SAME	

1.8. Device Description:

The Silk Road Medical ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter is a standard rapid exchange (RX) 0.014" Percutaneous Transluminal Angioplasty (PTA) catheter with a proximal single lumen and distal coaxial lumen tubing with a dilatation balloon, and an atraumatic, tapered tip. The proximal luer lock hub allows for connection with a balloon inflation device for inflation with diluted contrast medium. The second lumen in the distal shaft permits the use of an 0.014" guidewire to facilitate advancement of the catheter to and through the stenosis to be dilated. The balloon has two radiopaque marker bands to aid in positioning the balloon in the stenosis, located either 25 or 35 mm apart as indicated on the package label. An external position marker is located 32.5 cm from the distal tip to indicate the relative position of the catheter tip to the guiding catheter/introducer sheath. The total working length of the catheter is 75 cm. The Silk Road Medical ENROUTE Enflate Transcarotid RX Balloon Dilatation Catheter will complement the TCAR procedure.

1.9. Indications for Use:

The ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter is intended for percutaneous transluminal angioplasty and post-dilatation of self-expanding stents in the carotid arteries.

1.10. Summary of Performance Data

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding substantial equivalence of the device follows. Included in this section are descriptions of the testing performed on the subject ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter to support substantial equivalence to the predicate device:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- Sterilization, Packaging Validation, and Shelf Life

The subject, ENROUTE ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter met all established requirements.

1.10.1. Biocompatibility Testing

The subject ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter uses equivalent materials, processing, and identical sterilization methods as those in the predicate device, AVIATOR PLUS PTA Balloon Dilatation Catheter [K071189].

Biocompatibility testing was successfully conducted per BS EN ISO 10993-1. The studies were selected in accordance with ISO 10993-1 guidelines (Biological Evaluation of Medical Devices) for a limited exposure (< 24 hours), external communicating device with circulating blood contact. Studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices (GLP) and included:

- Cytotoxicity
- Intracutaneous reactivity (Irritation)
- Sensitization
- Acute systemic toxicity
- Hemocompatibility
    - Direct and Indirect Contact
    - Complement activation
    - In vivo thromboresistance
- Pyrogenicity

1.10.2. Design Verification – Bench-top Testing

The physical and mechanical properties of the ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter were assessed in accordance with FDA draft guidance “Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters – Premarket Notification (510(k)) Submissions” and the guidance "Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters- Class II Special Controls Guidance for Industry and FDA. Standard test methods and pre-determined acceptance criteria were used. The following tests were performed and all tests passed successfully:

- Visual and Dimensional Inspection
- Simulated Use
- Balloon Rated Burst Pressure
- Balloon Rated Burst Pressure (Without Stent)
- Balloon Fatigue
- Balloon Fatigue (Without Stent)
- Balloon Fatigue (In Stent)
- Balloon Compliance
- Catheter Bond Strength
- Tip Pull Test
- Flexibility and Kink Test
- Torque Strength

- Balloon Rated Burst Pressure (In Stent)
- Balloon Inflation and Deflation Time
- Radiopacity

1.10.3. Sterilization, Packaging Validation, and Shelf Life

Sterility testing demonstrated that the device is compliant with ISO 11135:2014 “Sterilization of health care products – Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices”.

Packaging validation conducted in accordance with ISO 11607-1 & ISO 11607-2, and design verification testing performed on accelerated aged devices were used to establish shelf life.

1.11. Summary of Substantial Equivalence

The subject, ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter is substantially equivalent to the predicate device with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes. Substantial equivalence was demonstrated with non-clinical performance tests, which complied with the requirements specified in the international and FDA-recognized consensus standards. The results of these tests demonstrate that ENROUTE Enflate™ Transcarotid RX Balloon Dilatation Catheter met the acceptance criteria, is adequate for the intended use, and is substantially equivalent to the predicate.