April 11, 2023

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

Re: K230402
Trade/Device Name: ENROUTE® Transcarotid Neuroprotection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: February 14, 2023
Received: February 15, 2023

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,

Misti L. Malone -S

Misti Malone, PhD
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

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)*
K230402/S001

Device Name
Enroute Transcarotid Neuroprotection System

Indications for Use *(Describe)*

The ENROUTE Transcarotid Neuroprotection System is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy described below:

- Adequate femoral venous access
- Common carotid artery reference diameter of at least 6mm
- Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomopgraphy (CT) angiography or magnetic resonance (MR) angiography.

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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1. 510(k) Summary

1.1. Date of Preparation of 510(k)Summary

February 14, 2023

1.2. Device Trade or Proprietary Name

1.3. Device Trade or Proprietary Name

Enroute Transcarotid Neuroprotection System

1.4. Device Classification

Regulatory Class: II
Classification Panel: Cardiovascular
Classification Name: Temporary Carotid Catheter for Embolic Capture
Commun Name: Percutaneous Catheter
Classification Regulation: 870.1250
Product Code: NTE

1.5. Predicate Device

510K Number & Date: K153485 on March 10, 2016
Device Name: Enroute Transcarotid Neuroprotection System

Predicate Device		
510(k) Number/ Clearance Date	**Name of Device**	**Name of Manufacturer**
K153485 cleared on March 10, 2016	ENROUTE® Transcarotid Neuroprotection System	Silk Road Medical 1213 Innsbruck Dr. Sunnyvale, CA 94089

1.6. Predicate Device Comparison

Predicate Comparison		
Device Name	**Predicate Device**	**Subject Device**
	ENROUTE® Transcarotid Neuroprotection System	**ENROUTE® Transcarotid Neuroprotection System (Modified)**
Indications For Use	The ENROUTE Transcarotid Neuroprotection System (ENROUTE Transcarotid NPS) is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy described below: • Adequate femoral venous access • Common carotid artery reference diameter of at least 6 mm • Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography.	SAME
Device Characteristics		
Single Use	Yes	SAME
Arterial and Venous Sheath reinforcement	Sheath body is reinforced with a ribbon coil	SAME

Predicate Comparison		
Device Name	**Predicate Device** **ENROUTE® Transcarotid Neuroprotection System**	**Subject Device** **ENROUTE® Transcarotid Neuroprotection System (Modified)**
Arterial and Venous Sheath construction	Sheath body outer jacket is mostly constructed of thermoplastic polymer layers of various densities to enhance flexibility	SAME
Arterial Sheath Configuration	• Straight • Angled-Tip	Angled-Tip
Sheath Stopper Design	• Removable • Large Distal Foot • Suture Grooves • Positive Lock to the Sheath	SAME
Venous Return Sheath components	• Sheath • Hemostasis Valve • Flow Line with Stopcock and Quick Connect • Dilator	SAME All return sheath components remain the same except that the stopcock now provides indexed tactile feedback.
Arterial Sheath Components	• Sheath • Hemostasis Valve • Extension Tubing • Arterial Stopcock • Dilator	SAME All sheath components remain the same except that the stopcock now provides indexed tactile feedback.
Guidewire Construction	• Core wire 0.035” OD • 90 cm PTFE-coated Nitinol with stainless steel coil J-Tip.	SAME
Dimensions		
Transcarotid Arterial Sheath		
Working Length	11 cm	SAME
Total Length	33.2 cm	SAME
Inner Diameter	8 Fr (2.6 mm)	SAME
Outer Diameter	10.5 Fr (3.5 mm)	SAME
Venous Return Sheath		
Working Length	11 cm	SAME
Total Length	13.6 cm	SAME
Inner Diameter	8 Fr (2.6 mm)	SAME

Predicate Comparison		
Device Name	**Predicate Device**	**Subject Device**
	ENROUTE® Transcarotid Neuroprotection System	**ENROUTE® Transcarotid Neuroprotection System (Modified)**
Outer Diameter	10.5 Fr (3.5 mm)	SAME
Arteriovenous Shunt		
Total Length	102 cm ± 2 cm	SAME
Packaging and Sterilization		
Packaging	Paperboard card Nylon/Tyvek pouch Paperboard shelf carton	Thermoformed, Plastic tray Nylon/Tyvek pouch Paperboard shelf carton
Sterilization	Ethylene Oxide (EO) SAL: 10^{-6}	SAME
Shelf Life	6 months at original submission (now labeled for 3-years)	6 months

1.7. Device Description:

The ENROUTE® Transcarotid Neuroprotection System (Modified) is designed to provide direct transcarotid arterial access to the common carotid artery (CCA), provide introduction of diagnostic agents and therapeutic devices, and provide embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis. The ENROUTE Transcarotid NPS (Modified) is designed to transport emboli away from the carotid artery circulation by reversing blood flow at the treatment site prior to crossing a lesion in the carotid artery and during lesion manipulation. It has an integrated filter used to capture and contain embolic material liberated during the procedure.

The ENROUTE Transcarotid NPS (Modified) consists of four primary components: the Transcarotid Arterial Sheath with Dilator, the Venous Return Sheath with Dilator, the Flow Controller and a 0.035" Extra Support J-Tip Guidewire. When assembled and inserted into the patient, the components of the ENROUTE Transcarotid NPS (Modified) create an arteriovenous shunt. When used in conjunction with occlusion of the proximal common carotid artery, the ENROUTE Transcarotid NPS (Modified) reverses the direction of blood flow in the internal carotid artery (ICA), shunting embolic particles away from the cerebral circulation, and into the venous circulation. Flow through the arteriovenous shunt is regulated by the Flow Controller.

1.8. Indications for Use:

The ENROUTE Transcarotid Neuroprotection System (ENROUTE Transcarotid NPS) is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have appropriate anatomy described below:

- Adequate femoral venous access
- Common carotid artery reference diameter of at least 6 mm
- Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography.

1.9. 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, which substantiates the safe and effective performance of the subject, ENROUTE® Transcarotid Neuroprotection System (Modified) as well its substantial equivalence to the predicate device:

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

The subject, ENROUTE® Transcarotid Neuroprotection System (Modified) met all established requirements.

1.9.1. Biocompatibility Testing

The purpose of biocompatibility testing is to demonstrate an absence of harmful effects of patient-contact materials in the subject device, ENROUTE® Transcarotid Neuroprotection System (Modified).

The materials used in the subject, ENROUTE® Transcarotid Neuroprotection System (Modified) are the same as those utilized in the currently marketed predicate device, ENROUTE® Transcarotid Neuroprotection System, with the exception of the new packaging tray. The ENROUTE® Transcarotid Neuroprotection System (Modified) device is manufactured in the same environment as the ENROUTE® Transcarotid Neuroprotection System and uses equivalent manufacturing processes.

Biocompatibility testing was successfully conducted per ISO 10993-1. The studies completed for the ENROUTE® Transcarotid Neuroprotection System (Modified) 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
- Hemocompatibility
    - Direct and Indirect Contact

All other biocompatibility risks were mitigated through successful completion of prior biocompatibility testing per EN ISO 10993-1:2009/AC: 2010, which was provided in the original 510k for the predicate device (K153485) and will be leveraged for the ENROUTE® Transcarotid

Neuroprotection System (Modified). Therefore, no further biocompatibility testing was required.

Cytotoxicity and Hemocompatibility (Direct and indirect hemolysis) testing were successfully completed on final, finished Arterial Sheath components of the full device. All tests received passing scores. Thus, the ENROUTE® Transcarotid Neuroprotection System (Modified) is considered biocompatible and meet the requirements of ISO 10993-1:2018: Biological evaluation of medical devices – Part 1.

1.9.2. Design Verification – Bench-top Testing

Design Verification testing was conducted to mitigate risks for the subject device, ENROUTE® Transcarotid Neuroprotection System (Modified), and to demonstrate substantial equivalence to the predicate. Testing was based on the design specifications, risk analysis, SOPs, Work Instructions, and available guidance/standards documents.

Design Verification testing was conducted to evaluate the physical and mechanical properties of the subject, ENROUTE® Transcarotid Neuroprotection System (Modified). All studies were conducted using good scientific practices and statistical sampling methods as required by Silk Road Medical Design Control procedures. All testing met the pre-determined acceptance criteria.

Performance testing for the subject device was performed in accordance with the standards with the following guidance:

- Guidance for Industry and Food and Drug Administration Staff Coronary and Carotid Embolic Protection Devices Premarket Notification [510(k)] Submissions

To support the modifications made, the subject ENROUTE® Transcarotid Neuroprotection System (Modified) device underwent the following performance testing:

- Visual Inspection and Dimensional Verification
- Liquid Leakage Under Pressure
- ISO 80369-7 Small Bore Connector Dimensional and Functional Testing
- DilatorSnap Force
- Dilator Peak Tensile Force
- Simulated Use/Usability
- Air Leakage During Aspiration
- Junction Tensile Strength
- Shelf-Life
- Packaging Testing

1.9.3. 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.

1.10. Summary of Substantial Equivalence

The subject device, ENROUTE® Transcarotid Neuroprotection System (Modified), is substantially equivalent to the predicate device, The ENROUTE® Transcarotid Neuroprotection System (K153485) in indications for use, operating principle, technology, design, materials, dimensions, physician use, single use, sterilization, and device biocompatibility.

The differences in design between the subject and predicate devices do not impact the overall principles of operation, how the device is used and where the device is used.

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® Transcarotid Neuroprotection System (Modified) met the acceptance criteria and is adequate for the intended use and does not raise new issues of safety and effectiveness.