DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 10, 2016

Silk Road Medical, Inc.
Ms. Kristin Ellis
Manager, Regulatory Affairs
735 North Pastoria Ave.
Sunnyvale, CA 94085

Re: K153485
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 9, 2016
Received: February 10, 2016

Dear Ms. Ellis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153485

Device Name
ENROUTE Transcarotid Neuroprotection System

Indications for Use *(Describe)*
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.

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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"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."

510(K) SUMMARY

A. Device Information

Category	Comments
Sponsor:	Silk Road Medical 735 N. Pastoria Avenue Sunnyvale, CA 94085
Correspondent Contact Information:	Primary: Kristin Ellis 735 N. Pastoria Avenue Sunnyvale, CA 94085 (408)857-0934 Alternate: Richard Ruedy 735 N. Pastoria Avenue Sunnyvale, CA 94085 (408) 828-7281
Device Common Name:	Temporary carotid catheter for embolic capture
Device Classification Number:	21 CFR§ 870.1250
Device Classification & Product Code:	Class II, NTE
Device Proprietary Name:	ENROUTE™ Transcarotid Neuroprotection System

Predicate Device Information:

Predicate Device:	ENROUTE™ Transcarotid Neuroprotection System
Predicate Device Manufacturer:	Silk Road Medical
Predicate Device Common Name:	Temporary carotid catheter for embolic capture
Predicate Device Premarket Notification #	K143072
Predicate Device Classification:	21 CFR§ 870.1250
Predicate Device Classification & Product Code:	Class II, NTE

B. Date Summary Prepared

December 2, 2015

C. Description of Device

Silk Road Medical, Inc. is the manufacturer of a single use device intended to provide embolic protection during carotid artery angioplasty and stenting procedures. The

ENROUTE Transcarotid NPS 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.

Like the predicate device, the ENROUTE Transcarotid NPS consists of three primary components: the ENROUTE Transcarotid Arterial Sheath, the ENROUTE Venous Return Sheath, and the ENROUTE Flow Controller. The Subject Device offers an Angled-Tip configuration and a Straight Tip configuration of the Transcarotid Arterial Sheath. When assembled, the ENROUTE Transcarotid NPS creates an Arteriovenous Shunt. The Transcarotid Arterial Sheath is placed in the carotid artery below the carotid bifurcation. The Venous Return Sheath is placed into the femoral vein. The Arterial and Venous Sheaths are connected by the Flow Controller, thereby completing the Arteriovenous Shunt. When the carotid artery is occluded just proximal to the Transcarotid Arterial Sheath insertion site, the arterial/venous pressure gradient diverts or reverses blood flow in the internal carotid artery (ICA) and external carotid artery (ECA) thereby directing the blood from the cerebral arteries through the Transcarotid Arterial Sheath, through the Flow Controller with integrated filter, and out through the Venous Return Sheath into the venous circulation.

The ENROUTE Transcarotid Arterial Sheath and ENROUTE Venous Return Sheath are constructed of stainless steel reinforced thermoplastic elastomers attached to hemostasis valve adaptors. The Angled-Tip Transcarotid Arterial Sheath configuration has a 15° bend at the distal tip whereas the Straight-Tip Transcarotid Arterial Sheath configuration has no bend at the distal tip. The ENROUTE Flow Controller consists of DEHP free PVC tubing with an integrated polyester filter and polycarbonate housing. A 90cm long 0.035” PTFE coated Nitinol with stainless steel coil J-Tip Guidewire is provided with the ENROUTE Transcarotid NPS. The guidewire is used to facilitate the insertion of the Transcarotid Arterial Sheath into the common carotid artery (CCA) and the Venous Return Sheath into the femoral vein.

The ENROUTE Transcarotid NPS is an ethylene oxide sterilized, non-pyrogenic, single-use prescription device.

D. Indications for Use

The Subject Device and Predicate Device indications for use are identical.

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.

E. Comparison to Predicate Device

The Silk Road Medical ENROUTE Transcarotid Neuroprotection System (NPS) is substantially equivalent in intended use, indications for use, operating principle, technology, reverse flow path resistance, design, materials, method of use and location of use, working length dimensions, principle operator, single use, sterilization, guidewire design, guidewire use and system biocompatibility to the Predicate Device, ENROUTE Transcarotid Neuroprotection System with Filter, (K143072).

The Subject Device and Predicate Device are based on the same technological elements:

- They both consists of three primary components: the ENROUTE Transcarotid Arterial Sheath, the ENROUTE Venous Return Sheath, and the ENROUTE Flow Controller.
- When connected, they both create an Arteriovenous Shunt
- They are both embolic protection systems featuring vascular proximal occlusion and reversal of flow at the treatment site as the means to prevent emboli from reaching distal vasculature during a carotid intervention

The following technological differences exist between the Subject and Predicate Devices:

- A coil reinforced Arterial Sheath with a new material for improved flexibility
- An Angled-Tip and Straight-Tip configuration of the Arterial Sheath
- New material, positive lock, suture grooves and improved stability for the Arterial Sheath Stopper
- A coil reinforced Venous Return Sheath for improved flexibility
- New materials and integrated function of the Side Arm with Stopcock into the Flow Line and Stopcock of the Venous Return Sheath
- Integrated Filter and Flow Line in the Flow Controller with new Flow Line material
- Addition of mechanism in Flow Controller to ensure Low flow for device preparation
- Arterial and Venous Dilators inner diameters sized to accommodate 0.035” Guidewire
- Improved user interface for Arterial and Venous Dilators hubs
- New core material with lubricious coating, reduced outer diameter and increased length of Guidewire

The technological differences do not impact the overall principles of operation, the flow resistance design specification, how the device is used, where the device is used, the size and working length of the sheaths, the reverse blood flow path, the overall arteriovenous shunt length or embolic protection.

Both devices are single use only and ethylene oxide sterilized.

The testing described below demonstrates that the subject and predicate devices are substantially equivalent and that the modifications do not raise any new questions regarding safety or efficacy.

F. Summary of Supporting Data

Performance testing for the Subject Device was performed in accordance with:

- Guidance for Industry and FDA Staff: "Coronary and Carotid Embolic Protection Devices - Premarket Notification [510(k)] Submissions" document issued on February 15, 2008
- ISO 10555-1:2013 "Sterile, single-use intravascular catheters - Part 1: General requirements"
- ISO 594-1:1986 "Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements"
- ISO 11607-1:2006[R]2010 "Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems [Including: Amendment 1 (2014)]"
- ISO 11607-2:2006[R]2010) "Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]"
- ISO 11070:2014 "Sterile single-use intravascular introducers, dilators and guidewires".

The following testing was performed:

Performance Testing:

- Visual Inspection and Dimensional Verification
- Disengagement Force Dilator to Hemostasis valve
- Guidewire Advancement
- Dilator Hub Functional Testing (ISO 594-1:1986)
- Sheath Stopper Removal
- Kink Resistance
- Hemostat Clamp and Unclamp
- Air Leakage During Aspiration (ISO 10555-1:2014 and ISO 11070:2014)
- Liquid Leakage Under Pressure (ISO 10555-1:2014 and ISO 11070:2014)
- High/Low Switch Cycling
- Flow Stop Button Cycling
- Tensile Tests (ISO 10555-1:2014 and ISO 11070:2014)
- Flow Rate Characterization
- Air Emboli and Solid Emboli Transportation Simulation
- Small and Large Particle Transport and Capture Efficiency
- System Preparation and Simulated Use
- Packaging Validation (ISO 11607-1:2006[R]2010 and ISO 11607-2:2006[R]2010)
- Shelf Life

Guidewire Performance and Integrity Testing:

- Tip Flexibility
- Flexing (ISO 11070:2014)
- Fracture (ISO 11070:2014)
- Coating Adhesion
- Tensile Strength (ISO 11070:2014)
- Corrosion (ISO 11070:2014)

All bench testing met the pre-determined acceptance criteria. The performance testing demonstrates that the Subject Device is substantially equivalent to the Predicate Device.

The biocompatibility evaluation for the ENROUTE Transcarotid NPS was conducted in accordance with the FDA Blue Book Memorandum #G-95-1 "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1:2009 "Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The Subject Device was determined to be biocompatible. The battery of tests included the following:

- Cytotoxicity: MEM Elution L-929 ISO/USP
- Sensitization: Maximum Sensitization (Guinea Pig)
- Irritation: ISO Intracutaneous Reactivity Test
- Systemic Toxicity: ISO Acute Systemic Injection
- Hemocompatibility:
    - Four Hour Thromboresistance Evaluation in Dogs
    - Complement Activation C3a and SC5b-9
    - Platelet and Leukocyte Count
    - Partial Thromboplastin Time
    - Hemolysis
- Genotoxicity:
    - Bacterial Mutagenicity Test- Ames Assay
    - *in vitro* Mouse Lymphoma Assay
    - *in vivo* Mouse Micronucleus Assay
- Pyrogenicity:
    - Material Mediated Pyrogen

The ENROUTE Transcarotid NPS is considered to be a circulating blood external communicating device with limited exposure (≤ 24 hours). Exceptions include the non-patient contacting components which are assembled around the outside of the blood-path tubing and include the Flow Controller Housing components.

Sterility testing demonstrated that the device is compliant with ISO 11135-1:20007 "Sterilization of health care products – Ethylene oxide - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices" and ISO 11135-2:2008 "Sterilization of health care products – Ethylene oxide - Part 2: Guidance on the application of ANSI/AAMI/ISO 11135-1".

Animal Testing

A GLP animal study was performed to evaluate the safety, performance and handling of the Subject Device, ENROUTE Transcarotid Neuroprotection System, in three (3) porcine models. Based on gross pathology and clinical pathology results, the safety acceptance criteria for the studies were met. Performance and handling observations were made based on detailed characteristics of the device. No untoward observations were found by the clinician.

Pre-Clinical Testing

An additional sheath insertion test was performed for the ENROUTE Transcarotid Arterial Sheath and Arterial Dilator on an excised cadaveric carotid artery to evaluate the acceptability of the Dilator to Sheath transitions. All insertions were rated as acceptable by an experienced Vascular Radiologist. There was no evidence of damage to the test samples post insertions.

Clinical Testing:

The preclinical animal study and performance testing showed that the Subject Device is comparable substantially equivalent to the Predicate Device, (equivalent in operating principles, technology, intended use and does not raise any new questions of safety and efficacy) and therefore additional clinical testing was not required to support the proposed changes.

G. Conclusion

The conclusions drawn from the pre-clinical animal study and non-clinical performance tests demonstrate the Subject Device is substantially equivalent to the Predicate Device.