April 12, 2018

Straub Medical AG
% Ms. Barbara Atzenhoefer
Principal Medical Research Scientist, Regulatory
NAMSA
400 Hwy 169 South, Suite 500
Minneapolis, MN 55426

Re: K172315
Trade/Device Name: Straub Endovascular System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW, DQX
Dated: March 9, 2018
Received: March 12, 2018

Dear Ms. Atzenhoefer:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth J. Cavanaugh -S

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)*
K172315

Device Name
Straub Endovascular System

Indications for Use *(Describe)*
When operated with a Rotarex S single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.

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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510(k) Summary

Applicant Information

Date Prepared:	April 10, 2018
Applicant:	Straub Medical AG Straubstrasse 12 CH 7323 Wangs, Switzerland
Contact Person:	Amy Ehlenfeldt, Manager Quality and Regulatory Compliance Telephone: +41 (0) 81 720 04 60 Fax: +41 (0) 81 720 04 61

Subject Device

Name of Device:	Straub Endovascular System
Common/Usual Name:	Peripheral Atherectomy Catheter
Classification Name:	Intraluminal Artery Stripper
Regulation:	21 CFR §870.4875
Regulatory Class:	Class II
Product Codes:	MCW and DQX

Predicate

MEDRAD Jetstream Atherectomy System K133023

Asahi Intecc Co. Ltd. Asahi Asato 30 guidewire K071721

Device Description

The Straub Endovascular System consists of:

- Rotarex®S catheter set which includes a Rotarex®S catheter, guidewire, collecting bag and drape. All are provided sterile and are for single use
- Drive System, consisting of the Control Unit, Motor and Foot switch. The Drive System serves to drive and control the rotational catheters.

Rotarex®S is an over-the-wire, percutaneous catheter. The catheter consists of a flexible braided shaft, a rotating head, and a rotating helix which runs the length of the catheter. A lumen for the passage of the supplied guidewire runs the entire length of the helix and through the head of the catheter. The catheter head is made up of two overlying metal cylinders, with two side openings.

The outer cylinder is connected to the rotating helix, and the inner cylinder to the catheter shaft. The helix and the catheter head rotate at approximately 40,000-60,000 rpm depending on the model, by means of a gear box in the catheter housing and a motor contained within the catheter handle driven by the Drive System. The rotating outer cylinder is fitted with facets at its foremost tip, which when rotating, serve to abrade occluding material lying in front of it. Concomitantly, the rotation of the catheter head creates a vortex in the blood which assists to further erode occluding material from the vessel lumen. The detached material is aspirated into the side openings of the overlying cylinders where it is further broken down within the head and then carried through the inner lumen into a collecting bag outside of the body.

Indications for Use

When operated with a Rotarex®S single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.

Comparison of Technological Characteristics

As compared to the predicate devices, the Straub Endovascular System has similar components, indications for use, and identical classification codes as the selected predicate devices. The Straub Endovascular System is comprised of similar patient contact materials and has undergone appropriate biocompatibility testing for its intended use. As with the predicate devices, the Rotarex®S Catheter Set components are provided sterile and are intended for single-use.

With respect to general device design and technological characteristics, the Straub Endovascular System is substantially equivalent to the selected predicate device, since it similarly uses a cutting tip controlled by an external control unit and allows for the removal of tissue, thrombus, and fluid via aspiration. A summary of the similarities and differences are shown below.

Catheter Predicate - Similarities and Differences		
Characteristic	**Straub Endovascular System**	**Predicate**
Intended Use	Atherectomy and thrombus removal	Atherectomy and thrombus removal
System Components	Catheter, console/control unit, guidewire, Collecting bag, sterile drape for motor	Guidewire, Collecting bag, console / control unit
Mechanism of Action	Front cutting / rotational	Front cutting / rotational
Catheter Diameter	6F: 2.00 mm 8F: 2.67 mm	XC 2.1/3.0: 2.1mm (3.0mm blades out) XC 2.4/3.4: 2.4mm (3.4mm blades out)
Catheter Length	6F: 110 or 135 cm 8F: 85 or 110 cm	XC 2.1/3.0: 135 cm XC 2.4/3.4: 120 cm
Max. Guidewire Dia.	0.018”	0.014”
Min. Introducer Size	6F Rotarex: 6-7 F 8F Rotarex: 8-9 F	XC 2.1/3.0: 7 F XC 2.4/3.4: 7 F
Enclosed Cutting Blades	Yes	No
Target speed	6F: 60,000 rpm 8F: 40,000 rpm	XC 2.1/3.0: 70,000 rpm XC 2.4/3.4: 70,000 rpm
Aspiration	Yes	Yes
Infusion	No	Yes
Sterilization Method	EtO	EtO

There are no significant technological differences among the subject device and the predicate device. Therefore, the Straub Endovascular System is substantially equivalent to the Jetstream Atherectomy System.

Performance Testing Summary

The following testing was performed to demonstrate that the system and its components perform as intended:

Design verification and bench validation testing:

Rotarex®S system: Visual and Dimensional Inspections, Dynamic (Durability) Test Under Simulated Use Conditions, Tensile Test, Torsional Strength, Kink Test, Corrosion Resistance, Temperature Rise (heat generation) Testing, Aspiration Capacity, FAS (Helix) Integrity, Stator Coating Integrity, In vitro Calcified Plaque and Thrombus Removal Studies, Rotational Speed (speed stability).

Guidewire: Visual and Dimensional Inspections, Corrosion resistance, Fracture Testing, Bending, Tensile Strength, Tip Flexibility, Torque Response, Torque Strength, Radiopacity

Shelf-life was established at 3-years based on accelerated aging studies.

Biocompatibility testing was conducted on the catheter and guidewire in accordance with ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (and related sub-parts). Testing and included Cytotoxicity, Acute Systemic Toxicity, Sensitization, Intracutaneous Reactivity, Complement Activation, Hemolysis and Material-mediated Pyrogenicity.

Sterilization validations of the catheter and guidewire were conducted in accordance with ISO 11135-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

Electrical safety and Electromagnetic compatibility testing was conducted and the system determined to be compliant with the requirements of IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

A GLP animal study was conducted to assess the safety of the Straub Endovascular System in a porcine model. The following were assessed: procedure and device handling data, clinical pathology, adverse events, gross necropsy, histopathology and vascular injury score.

Clinical Testing

A meta-analysis of 8 clinical studies comprising data obtained from 2,107 patients studied from 2002 to 2015 was performed to establish Rotarex® S clinical performance. The purpose of the statistical summary of the literature data was to provide a quantitative review and synthesis of the results of related, but independent, studies of the Rotarex device. The analyses allowed for the estimation of various clinical outcomes including, but not limited to technical and clinical success, target lesion revascularization, restenosis rates, ankle-brachial index, Rutherford score and procedure-related adverse events.

Conclusions

The data and information presented within this submission and the similarities between the subject and predicate device support a determination of substantial equivalence, and therefore market clearance of the subject Straub Endovascular System through this 510(k) Premarket Notification.