December 7, 2018

Tractus Vascular LLC
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K180889
Trade/Device Name: Tractus Crossing Support Catheter (CSC)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 29, 2018
Received: October 30, 2018

Dear Janice Hogan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Lydia S. Glaw -S, 0.9.2342.19200300.100.1.1=2001460079
Date: 2018.12.07 15:07:23 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180889

Device Name
Tractus Crossing Support Catheter (CSC)

Indications for Use *(Describe)*
The Tractus CSC is intended to be used during interventional procedures in the coronary and peripheral vasculatures to support a guidewire and facilitate access in discrete regions, allow for guidewire exchanges, and provide a conduit for delivering saline solutions and contrast media.

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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510(k) SUMMARY – K180889

Tractus Vascular LLC's Crossing Support Catheter (CSC)

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Janet Burpee, CEO
Tractus Vascular, LLC.
15 Christopher Way
Eatontown, NJ 07724
Phone: 732-996-8513

Date Prepared: November 27, 2018

Name of Device

Crossing Support Catheter (CSC)

Common or Usual Name

Percutaneous Crossing Catheter

Classification Name:

21 CFR 870.1250, Class II, product code DQY

Predicate Devices

Quick Cross® Extreme Support Catheters (K092396) (Primary Predicate)

TOTAL across™ (K133539) (Reference Predicate)

Primi™ Support Catheter (K132701) (Reference Predicate)

Intended Use/Indications for Use

The Tractus CSC is intended to be used during interventional procedures in the coronary and peripheral vasculatures to support a guidewire and facilitate access in discrete regions, allow for guidewire exchanges, and provide a conduit for delivering saline solutions and contrast media.

Device Description

The CSC consists of a family of single-lumen, over-the-wire catheters offered in a variety of sizes for compatibility with a range of guidewire as well as effective lengths. The catheters are used to navigate tortuous peripheral and coronary vasculatures while providing axial stability to enhance guidewire crossing of discrete lesions of the vasculature. The catheters are also used to allow for guidewire exchanges, and provide a conduit for delivering saline solutions and contrast media.

Technological Characteristics

The CSC has similar technological characteristics as its predicate devices. Both the CSC and the primary predicate are single lumen, over-the-wire catheters that include a luer hub to allow for flushing of saline solutions and contrast media. Both the CSC and primary predicate facilitate guidewire exchanges and are compatible with 0.014" and 0.018" guidewires for use in the peripheral and coronary vasculatures under fluoroscopy with 4F sheaths. Furthermore, both the CSC and the primary predicate allow for device visualization using 3 visual bands and feature tapered distal tips.

The overall construction of both the CSC and the primary predicate are similar. Both catheters consist of an outer, inner, and center tubing configuration. The outer tubing of both the subject device and primary predicate consist of Pebax with hydrophilic coating on the distal end to reduce frictional forces and enhance tracking. The inner tubing of both the subject device and the primary predicate is a PTFE liner. Further, the material composition of the center tubing for both the subject and primary predicate is the same (i.e. stainless steel), with slightly different configurations (spiral laser cut versus braided). Despite this difference in configuration the principle of operation is the same. Furthermore, the spiral laser cut inner tubing design of the subject device has been cleared for the TOTAL across reference predicate (K133539) which was also cleared for substantially the same indications for use as the subject device.

The overall dimensions of the subject device and the primary predicate are similar. The subject device has slightly longer working length range than the primary predicate (90 – 170 cm for the subject device versus 90 - 150 cm for the primary predicate). However, similar working lengths have been cleared for the Primi Catheter reference predicate (90 cm to 170 cm) which was cleared for a nearly identical indication for use compared to the subject device.

Both the subject device and the primary predicate are provided sterile via EO sterilization and are non-pyrogenic. Further, both devices are packaged in Tyvek pouches.

Therefore, the subject CSC has very similar technological characteristics as the primary predicate, as well as the reference devices.

Performance Data

The following nonclinical performance testing has been conducted to support the substantial equivalence of the CSC to its predicate devices. In all instances, the CSC functioned as intended.

- Biocompatibility of the patient-contacting components of the device was established in accordance with ISO 10993.
- Anticoagulated porcine thromboresistance study
- Shipping simulation, environmental conditioning, and package integrity studies were completed.
- Functional bench testing was conducted (including demonstrated compliancewith relevant standards such as ISO 10555-1 and ISO 594-1).

- Simulated Use Testing was completed to demonstrate functional performance specifications were met.
- Coating Integrity (Blue Dye Test, Lubricity)
- Radiopacity Testing
- Particulate Testing
- Flexibility
- Trackability
- Guidewire Compatibility
- Retraction
- Torque Testing
- Particulate Testing

Substantial Equivalence

The CSC has the same intended use as the primary predicate device and substantially the same indications for use as the reference devices. The subject device also has similar technological characteristics and principles of operation as the predicate devices. Minor differences, including device sizing, materials, number and location of radiopaque markers, do not raise different questions of safety or effectiveness and performance testing demonstrated that the subject device performs in a substantially equivalent manner. Therefore, the subject CSC is substantially equivalent to its predicate devices.

Conclusions

Tractus Vascular LLC's CSC is a Percutaneous Catheter, Class II device that has been evaluated in nonclinical testing in accordance with FDA's recognized standards and pre-established acceptance criteria. Testing demonstrated that the device performs as intended. The CSC is substantially equivalent to its predicate devices.