August 5, 2019

Tractus Vascular LLC
Sam Gilbert
Manager, Regulatory/Clinical/Quality
15 Christopher Way
Eatontown, New Jersey 07724

Re: K183305
Trade/Device Name: Crossing Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 10, 2019
Received: July 11, 2019

Dear Sam Gilbert:

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,

for Kenneth Cavanaugh
Acting Director
DHT2C: Division of Coronary
and Peripheral Interventional 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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K183305

Device Name

Tractus Crossing Support Catheter

Indications for Use *(Describe)*

The Tractus CSC is intended to be used during interventional procedures in the peripheral vasculature 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 – K183305

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: July 30, 2019

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 (K082561) (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 peripheral vasculature 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 and sheath sizes as well as effective lengths. The subject device is a 0.035" guidewire compatible catheter with a 4.5 Fr crossing profile and available effective lengths of 90, 135, 155, and 170 cm. The catheters are used to navigate tortuous peripheral vasculature 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.

The CSC consists of an outer, inner, and center tubing configuration. The outer tubing of the CSC consists of Pebax with hydrophilic coating on the distal end of the catheter to reduce frictional forces and enhance tracking. The inner tubing consists of a PTFE liner and Pebax. The

center tubing is spiral laser cut stainless steel. This design provides catheter flexibility, kink resistance and torsional strength while also providing axial stability to support a guidewire and allow for guidewire placement across discrete lesions for further percutaneous intervention, such as angioplasty or stent placement. The distal tip of the catheter, which is stainless steel covered with Pebax and is continuous with the stainless steel center tubing of the catheter, has a smooth, rounded, and tapered profile that provides a seamless catheter-to-guidewire transition.

All effective lengths of the CSC include three radiopaque marker bands that are evenly spaced 10cm apart along the distal end of the catheter including one radiopaque marker band within 4mm of the distal end of the catheter for fluoroscopic visualization of the distal tip. In addition to providing hub-to-tip visualization of the catheter, the marker bands assist in catheter positioning and aide in estimating geometry within the vascular system for subsequent therapies, such as PTA and/or stenting. The proximal end of the catheter includes a luer hub to allow for guidewire passage, flushing saline solution or contrast media through the inner lumen of the catheter, and to facilitate guidewire exchanges.

To use the device, the inner lumen of the catheter is flushed with saline until the solution exits the distal end of the device prior to use. The appropriate size guidewire is inserted into the distal end of the catheter and the catheter is advanced over the guidewire and through a sheath using standard interventional techniques. Under fluoroscopic guidance, the catheter is tracked to the target site within the vasculature and utilized to support guidewire access across discrete areas of the vasculature using standard interventional techniques. For guidewire exchanges, standard interventional techniques are used. Saline or contrast media can be infused into the catheter during operation for flushing and fluoroscopic visualization. Once guidewire access across the target lesion is gained, the catheter is withdrawn using standard interventional techniques.

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 0.035” guidewires for use in the peripheral vasculature under fluoroscopy with 5F sheaths. Furthermore, both the CSC and the primary predicate allow for device visualization using three (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, albeit marketed for a 0.014” guidewire compatible catheter only.

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

- Acute Systemic Toxicity
- Materials-Mediated Pyrogenicity
- Intracutaneous Irritation
- Maximization Sensitization
- MEM Elution
- Hemolysis – Extract Method
- Hemolysis – Direct Contact Method
- Nonanticoagulated Canine Thromobgenicity
- Anticoagulated Porcine Thrombogenicity
- Complement Activation (SC5b-9)
- Simulated Use Testing
- Flexibility
- Trackability
- Guidewire Compatibility
- Torque Tolerance
- Tensile Strength
- Bond Strength
- Coating Integrity (Blue Dye Test, Lubricity)
- Radiopacity
- Particulate Emission
- Flow Rate
- Corrosion Resistance
- Package Integrity
- Shipping Simulation
- Environmental Conditioning
- Bubble Leak
- Seal Strength

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 substantially the same technological characteristics and principles of operation as the predicate devices. Any minor differences 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.