January 19, 2023

Tractus Vascular, LLC
Janet Burpee, CEO/CTO
20 Meridian Road, Unit 9B
Eatontown, New Jersey 07724

Re: K221163
Trade/Device Name: Tunnel Crossing Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: December 15, 2022
Received: December 19, 2022

Dear Janet Burpee:

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,

Samuel G. Raben -S

for Lydia Glaw
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

Enclosure

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)*
K221163

Device Name
Tunnel Crossing Catheter (Tunnel CC)

Indications for Use *(Describe)*
The Tunnel CC is intended to be used with a guidewire to access discrete regions of the peripheral vasculature and to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

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

Tunnel™ Crossing Catheter

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

Janet Burpee, CEO
Tractus Vascular, LLC.
20 Meridian Road, Unit 9B
Eatontown, NJ 07724
Phone: (732) 590-1470

Date Prepared: April 20, 2022

Name and Classification of Device

Name of Device: Tunnel™ Crossing Catheter (*Tunnel CC* or Subject Device)

Common Name: Percutaneous Crossing Catheter

Classification Name: 21 CFR 870.1250, Class II, product code PDU

Predicate Devices

Primary Predicate: Medtronic Vascular's Viance™ Catheter (K120533)

Reference Predicate**:** Tractus™ Crossing Support Catheter (K180889 & K183305)

Device Description

The *Tunnel CC* is a single lumen, over-the-wire endovascular catheter. The design consists of a layered tubing configuration with a hydrophilic, lubricious coating on the distal end to reduce frictional forces. The center stainless steel (SS) tubing which drives functionality including buckling resistance is cut in a continuous spiral jigsaw pattern along most of the length; it ends with longitudinal laser cuts at the distal end enabling the formation of a smooth, tapered tip that is continuous with the shaft body of the catheter. This center SS tube is sandwiched between two polymer tubes where the inside layer is PTFE and the outside layer is PEBAX. A luer hub at the user end allows flushing of saline solutions or contrast media through the inner lumen and facilitates guidewire exchanges. This device

comes in 0.014”, 0.018” and 0.035” guidewire compatible sizes and lengths of 90-cm, 135-cm, 155-cm and 170-cm for each guidewire size.

The catheters are used to navigate tortuous peripheral vasculature while providing axial stability to enhance guidewire and device crossing of discrete lesions of the peripheral vasculature. The catheters are also used to allow for guidewire exchanges and provide a conduit for delivering saline solutions and contrast media.

Intended Use/Indications for Use

The Tunnel CC is intended to be used with a guidewire to access discrete regions of the peripheral vasculature and to facilitate the intraluminal placement of conventional guidewires beyond stenotic peripheral lesions (including chronic total occlusions) prior to placement of other interventional devices.

Technological Characteristics

The Subject Device and the Reference Predicate are the *same device with no proposed changes* and is described below.

This device is a single lumen, over-the-wire catheter. The design consists of a layered tubing configuration. The center tubing is stainless steel which is cut in a continuous jigsaw spiral pattern with a laser cut distal end which is formed to a smooth, tapered tip that is continuous with the shaft body of the catheter (i.e. no bonds). This center tube is sandwiched between two polymer tubes where the inside layer is PTFE and the outside layer is PEBAX; both inner and outer polymer tubes are common catheter materials. A luer hub at the user end allows flushing of saline solutions or contrast media through the inner lumen and facilitates guidewire exchanges. The catheter has a lubricious coating on the distal portion to reduce frictional forces. Both the Subject Device and the Reference Predicate consist of 0.014”, 0.018” and 0.035” guidewire compatible sizes and lengths of 90-cm, 135-cm, 155-cm and 170-cm with a total matrix of 12 configurations.

The overall construction of both the Subject Device and Primary Predicate are similar. Both devices (a) consist of an outer, inner, and center tubing configuration; (b) have an inner and outer tubing consisting of Pebax; (c) have a PTFE inner liner; (d) have a center tubing consisting of stainless steel; and (e) a hydrophilic coating on the distal end to reduce frictional forces and enhance tracking. The stainless-steel center tubing for the Subject Device consists of a spiral, laser cut configuration. Comparatively, the stainless-steel center tubing of the Reference Predicate is coiled. The Primary Predicate includes a torque device, coaxially positioned over the outer shaft at the proximal portion. The Subject Device does not provide a torque device. Nonetheless, the principle of operation is the same where both features provide increased catheter flexibility and kink resistance, which is required for navigating tortuous peripheral vasculature while also providing axial stability to enhance crossing of stenotic and occlusive lesions in the vasculature.

Both devices are packaged in Tyvek pouches and provided sterile for single use.

Performance Data

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

- All of the following was demonstrated for the 510(k)-Cleared-Indication, and therefore, demonstrated for the Subject Device.
    - Biocompatibility of the patient-contacting components of the device was established in accordance with ISO 10993.
    - Shipping simulation, environmental conditioning, and package integrity studies were successfully completed.
    - Functional bench testing was conducted (including demonstrated compliance with relevant standards such as ISO 10555-1 and ISO 594-1) and was cleared for the Primary Predicate.
    - Simulated use testing to assess the tracking, flexibility, torquability and guidewire exchange was completed to demonstrate functional performance specifications were met and cleared for the Primary Predicate.
- Equivalency to the Primary Predicate's ability to support a guidewire and facilitate access in discrete regions was demonstrated for the Expanded-Indication as follows.
    - Functional bench testing to demonstrate buckling and kink resistance.

- Simulated use testing to assess the ability to cross a mock lesion was successfully completed.

Conclusions

The *Tunnel CC* 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. Performance tests on the Subject Device related to the 510(k)-Cleared-Indication and Expanded-Indication are compared to the Primary Predicate and Reference Predicate, respectively. Testing demonstrated that the device performs as intended. The *Tunnel CC* is substantially equivalent to the referenced predicates.