May 29, 2020

Transit Scientific
Spencer Walker
Director of Regulatory Affairs
University of Utah
10 North 1900 East, EHSL Rm. 22B
Salt Lake City, Utah 84112

Re: K193420
Trade/Device Name: XO Cross Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY

Dear Spencer Walker:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 6, 2020. Specifically, FDA is updating this SE Letter to reflect that changes have been implemented to your 510(k) Summary to remove proprietary information.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Lydia Glaw, OHT2: Office of Cardiovascular Devices, 301-796-1456, or Lydia.glaw@fda.hhs.gov.

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

May 6, 2020

Transit Scientific
Spencer Walker
Director of Regulatory Affairs
University of Utah
10 North 1900 East, EHSL Rm. 22B
Salt Lake City, Utah 84112

Re: K193420/S001
Trade/Device Name: XO Cross Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 3, 2020
Received: April 6, 2020

Dear Spencer Walker:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2020.05.06 16:33:27 -04'00'

Lydia Glaw
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number (*if known*)
K193420

Device Name

XO Cross Support Catheter

Indications for Use (*Describe*)

The XO Cross is a support catheter intended to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

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.

510(k) Summary

Submitter: Transit Scientific, LLC.

Contact Person*:* Spencer Walker, MSC – Director Regulatory Affairs
Center for Medical Innovation
10 North 1900 East, Rm 22B
Salt Lake City, UT 84112
(801) 581-5080

Date Prepared: December 5, 2019

Trade Name: XO Cross Support Catheter

Classification Name*:* Percutaneous Catheter
21 CFR §870.1250, Product Code DQY

Device Class: Class II

Predicate Device:

- K082561 – Quick-Cross Extreme Support Catheter, Spectranetics Corporation, Inc.

Device Description:

The XO Cross catheter is a single-lumen support catheter designed to support a guidewire during access of the peripheral vasculature, allowing for exchange of guidewires during vascular access procedures, and providing a conduit for the delivery of saline solutions or diagnostic contrast agents. The shaft and tip are both radiopaque to track the location of the *XO Cross* catheter within the vasculature, while under fluoroscopy. It is available in various lengths (90cm, 135cm, 150cm, 175cm) and ranges in diameter from 2 Fr (0.7 mm) to 4 Fr (1.35 mm) with a tapered polymer tip at its distal end.

Indications for Use:

The XO Cross is a support catheter intended to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Comparative Analysis:

It has been demonstrated that the XO Cross catheter is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The XO Cross catheter has been fully assessed within the Transit Scientific Risk Management and Design Controls systems. All

necessary verification steps met pre-determined acceptance criteria to confirm substantial equivalence.

It has been demonstrated that the XO Cross is comparable to the predicate device in the following manner:

- Same intended use
- Same indications for use
- Same fundamental scientific technology
- Same or similar material properties
- Same operating principle
- Same or similar performance specifications
- Same or similar patient-user interface

Table 1: Substantial Equivalence Comparison Chart

	Predicate – K082561 (Quick-Cross Catheter)	**Subject Device: *XO Cross* Catheter**
Ind. for Use	Quick-Cross Extreme Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.	The XO Cross is a support catheter intended to guide and support a guidewire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.
Classification Name	Cardiovascular Device – Percutaneous Catheter 21 CFR §870.1250 Product Code: DQY Class II	Same
Single Use	Yes	Same
Fundamental Scientific Technology	Single	Same
Prescription (Rx Only)	Yes	Same
Anatomical Access	Peripheral Vasculature	Same
Design	Single Lumen SS braided shaft w/ straight or angled tip. Distal 40 cm coated with hydrophilic coating.	Single Lumen metal alloy hypo-tube shaft w/ tapered tip and polymer jacket.
Effective Length (cm)	65, 90, 135, 150	90, 135, 150, 175
Catheter Sizes	4Fr	2Fr - 4Fr
Distal Tip Profile	1.9 Fr, 2.1Fr, 3.2Fr	1.6Fr, 1.9Fr, 3.2Fr
Shaft Outer Diameter	0.034”, 0.038”, 0.053”	0.029”, 0.037”, 0.051”

Table 1: Substantial Equivalence Comparison Chart		
	Predicate – K082561 (Quick-Cross Catheter)	**Subject Device: *XO Cross* Catheter**
Visibility	3 radiopaque markers	Radiopaque catheter body, 40% tungsten loading polymer tip
Guidewire Compatibility	0.014", 0.018", 0.035"	Same
Sheath / Introducer Compatibility	4 Fr, 5 Fr	4Fr
Max Infusion Pressure	300 psi, 500psi	Tested for manual infusion, not for use with power injectors.
Sterility	Sterile – EO	Same
Biocompati-bility	ISO 10993	Same

Functional/Safety Testing:

The following functional tests were performed. All data met pre-determined acceptance criteria.

- **Biocompatibility** – Biocompatibility of the complete and finished *XO Cross* catheter has been verified according to the requirements and testing prescribed in ISO 10993-1 and in accordance with FDA guidance document "Use of International Standard ISO 10993-1" for an external communicating device with limited exposure (<24hrs) to circulating blood. Per ISO 10993-1, testing included the following:
  - *Cytotoxicity*
  - *Irritation/ Intracutaneous Toxicity*
  - *Sensitization*
  - *Systemic Injection*
  - *Material Mediated Pyrogenicity*
  - *Hemolysis Complete*
  - *Complement Activation*
  - *Thrombogenicity*

- **Design Verification** –The XO Cross models all meet or exceeded both Transit Scientifics in-house requirements, and requirements listed in ISO 10555-1. Packaging integrity was validated in conjunction with the sterilization studies.

Conclusion:

The XO Cross support catheter is substantially equivalent to the cited predicate device. Additionally, the XO Cross support catheter met all acceptance criteria to confirm substantial equivalence.