April 11, 2022

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

Re: K214107
Trade/Device Name: XO CROSS CORONARY Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 16, 2022
Received: March 18, 2022

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,

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)*
K214107

Device Name
XO Cross Coronary Support Catheter

Indications for Use *(Describe)*
The XO Cross Coronary is a support catheter intended to guide and support a guidewire during access of the peripheral or coronary 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.

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510(K) SUMMARY

(21 CFR 807.92)

GENERAL INFORMATION

Submitter: Transit Scientific, LLC

Contact Person*:* Spencer Walker, MSc – Director of Regulatory Affairs
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Date Prepared: March 16, 2022

Trade Name: *XO Cross Coronary* Support Catheter

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

Device Class: Class II

Predicate Device: 510(k) No.: K092396
Model: Quick Cross Extreme Support Catheter
Manufacture: Spectranetics Corporation
Classification: DQY

Reference Device: 510(k) No.: K210322
Model: XO Cross Support Catheter
Manufacture: Transit Scientific, LLC
Classification: DQY

Device Description:
The XO Cross Coronary Support Catheter is a single-lumen support catheter designed to support a guidewire during access of the peripheral or coronary 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 Coronary* Support Catheter within the vasculature, while under fluoroscopy. The distal end of the subject catheter is also coated with a hydrophilic coating to reduce surface friction. It is available in various lengths (90cm, 135cm, 150cm, 175cm), with a diameter of 2 Fr (0.7 mm) and with a tapered polymer tip at its distal end.

Table 1: XO Cross Coronary Support Catheter Model Numbers		
Product Family	**Model No.**	**Description**
XO Cross Coronary Support Catheter	CC-090-H	*XO Cross Coronary* – 0.014-inch diameter catheter shaft in 90cm, 135cm, 150cm and 175cm lengths.
	CC-135-H	
	CC-150-H	
	CC-175-H	

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

Comparative Analysis:
Modifications to the previously 510(k) cleared XO Cross Support Catheter (K210322) resulted in a new indication for use (i.e. use in coronary vasculature). To support this change a few minor modifications in design were made which resulted in new the product codes. The following modifications were made to the subject catheter:

- Longer Tapered Tip
- Modified Strain Relief
- Outer polymer layer color changes to black
- Minimum Kink Specifications
- Minimum Tip ID and Tensile Specifications

It has been demonstrated that the modified XO Cross Coronary catheter is comparable to the predicate device in fundamental scientific technology, design, materials, principles of operation and functional performance evaluations and is substantial equivalent as summarized in **Table 2**. Furthermore, the XO Cross Coronary catheter has been fully assessed within the Transit Scientific Risk Management and Design Controls systems. The differences raise no additional or different questions of safety or effectiveness from that already identified for the predicate device.

Table 2: Substantial Equivalence Comparison Chart			
	Predicate – K092396 (Quick-Cross Catheter)	**Reference – K210322 (XO Cross Support Catheter)**	**Subject Device – *XO Cross Coronary* Support Catheter**
Intended Use	The Intended patient population is those suffering from vascular disease, both coronary and peripheral.	The Intended patient population is those suffering from vascular disease.	The Intended patient population is those suffering from vascular disease, both coronary and peripheral.
Ind. for Use	Quick-Cross Extreme Support Catheters are intended to guide and	The XO Cross is a support catheter intended to guide and support a guidewire	The XO Cross Coronary is a support catheter intended to guide and support a

Table 2: Substantial Equivalence Comparison Chart			
	Predicate – K092396 (Quick-Cross Catheter)	**Reference – K210322 (XO Cross Support Catheter)**	**Subject Device – *XO Cross Coronary* Support Catheter**
	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.	during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.	guidewire during access of the peripheral or coronary 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	Cardiovascular Device – Percutaneous Catheter 21 CFR §870.1250 Product Code: DQY Class II	Cardiovascular Device – Percutaneous Catheter 21 CFR §870.1250 Product Code: DQY Class II
Single Use	Yes	Yes	Yes
Fundamental Scientific Technology	Provide support for guidewire placement and fluid administration	Provide support for guidewire placement and fluid administration	Provide support for guidewire placement and fluid administration
Prescription (Rx Only)	Yes	Yes	Yes
Anatomical Access	Peripheral or Coronary Vasculature	Peripheral Vasculature	Peripheral or Coronary Vasculature
Design	Single Lumen SS braided shaft w/ straight or angled tip. Distal end coated with hydrophilic coating.	Single Lumen metal alloy tube laser cut shaft w/ tapered tip and white polymer outer layer, with hydrophilic coating	Single Lumen metal alloy tube laser cut shaft w/ tapered tip and black polymer outer layer, with hydrophilic coating
Effective Length (cm)	65, 90, 135, 150	90, 135, 150, 175	90, 135, 150, 175
Distal Tip/ Crossing Profile	1.9 Fr, 2.1Fr, 3.2Fr	1.6Fr, 1.9Fr, 3.2Fr	1.6Fr
Shaft Outer Diameter	0.034”, 0.038”, 0.052	0.029”, 0.037”, 0.051”	0.029”
Visibility	3 radiopaque markers	Radiopaque catheter body, polymer tip with radiopaque filler	Radiopaque catheter body, polymer tip with radiopaque filler
Guidewire Compatibility	0.014”, 0.018”, 0.035”	0.014”, 0.018”, 0.035”	0.014”
Sheath / Introducer Compatibility	4 Fr and 5 Fr	2.9Fr and 4Fr	2.9Fr
Max Infusion Pressure	300 psi, 500psi	Tested for manual infusion, not for use with power injectors.	Tested for manual infusion, not for use with power injectors.
Sterility	Sterile – EO	Sterile – EO	Sterile – EO
Biocompatibility	ISO 10993	ISO 10993	ISO 10993

Functional/Safety Testing:

Verification activities were performed on the subject XO Cross Coronary Support Catheter to demonstrate substantial equivalence to the predicate device:

- **Biocompatibility** – The subject XO Cross Coronary is manufactured using the same materials and processes except for the black polymer outer layer as compared to the reference XO Cross which was manufactured with a white polymer outer layer on the OD of the catheter shaft. The additional biocompatibility testing was completed for the subject device in accordance with the 2020 FDA guidance document "Use of International Standard ISO 10993-1" for an external communicating device with limited exposure (≤ 24hrs) to circulating blood. The following tests were performed and passed:
    - Cytotoxicity
    - Sensitization
    - Intracutaneous Reactivity
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity
    - Bacterial Endotoxin LAL
    - Hemolysis
    - Complement Activation
    - Partial Thromboplastin Time (PTT)
    - Blood Platelet and Leukocyte Count

- **Design Verification** – Performance bench testing was conducted to ensure that the XO Cross Coronary Catheter met the applicable design and performance requirements throughout its shelf life, verify conformity to applicable standards, and demonstrate substantial equivalence to the predicate and reference devices. The following performance testing was performed or fulfilled with the XO Cross Coronary Catheter.
    - Tip ID Testing
    - Tip Tensile Testing
    - Distal Shaft Kink Testing
    - Simulated Use
- **Packaging –** The proposed changes to the XO Cross Support Catheter did not affect the packaging or its configuration.

Conclusion:
The subject XO Cross Coronary Support Catheter is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate and reference devices. The minor differences between the subject XO Cross Coronary Support catheter and the predicate and reference devices have no effect on safety or effectiveness, as established through various performance tests.