October 21, 2021

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: K210322
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: October 24, 2021
Received: September 22, 2021

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 and Part 809); 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)*
K210322

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.

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510(k) Summary

Submitter: Transit Scientific, LLC

Contact Person*:* Spencer Walker, MSc – Director of Regulatory Affairs
University of Utah/ Center for Medical Innovation
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(801) 581-5080
Spencer.walker@hsc.utah.edu

Date Prepared: March 19, 2021

Trade Name: *XO Cross* Support Catheter

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

Device Class: Class II

Predicate Device:

510(k) No.: K193420
Model: XO Cross Support Catheter
Manufacture: Transit Scientific, LLC
Classification: DQY

Device Description:

The XO Cross Support Catheter is identical to the predicate device in that it 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* 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) 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.

Table 1: XO Cross Support Catheter Part Numbers		
Product Family	**Catalog No.**	**Description**
XO Cross Support Catheter	C14-090	*XO Cross* 014 – 0.014-inch diameter catheter shaft in 90cm, 135cm, 150cm and 175cm lengths.
	C14-135	
	C14-150	
	C14-175	
	C18-090	*XO Cross* 018 – 0.018-inch diameter shaft, in 90cm, 135cm, 150cm and 175cm lengths.
	C18-135	
	C18-150	
	C18-175	
	C35-090	*XO Cross* 035 – 0.035-inch diameter shaft, in 90cm, 135cm, 150cm and 175cm lengths.
	C35-135	
	C35-150	
	C35-175	

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:

Modifications in design and materials of the previously 510(k) cleared XO Cross Support Catheter (K193420) did not result in new product codes. The following modifications were made to the subject catheter:

- Polymer Tip Extrusion radiopaque filler % increase, for increased radiopacity for improved visibility
- Addition of Hydrophilic Coating on distal portion of catheter to reduce surface friction
- Micro-cut refinements for better manufacturability

It has been demonstrated that the modified XO Cross catheter is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations and is substantial equivalent as summarized in **Table 2**. Furthermore, the modified XO Cross 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 – K193420 (XO Cross Support Catheter)	**Subject Device – K210322 *XO Cross* Support Catheter**
Ind. 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.	Same
Classification Name	Cardiovascular Device – Percutaneous Catheter 21 CFR §870.1250 Product Code: DQY Class II	Same
Single Use	Yes	Same
Fundamental Scientific Technology	Provide support for guidewire placement and fluid administration	Same
Prescription (Rx Only)	Yes	Same
Anatomical Access	Peripheral Vasculature	Same
Design	Single Lumen metal alloy tube laser cut shaft w/ tapered tip and polymer outer layer.	Single Lumen metal alloy tube laser cut shaft w/ tapered tip and polymer outer layer, with hydrophilic coating.
Effective Length (cm)	90, 135, 150, 175	Same
Catheter Sizes	2Fr - 4Fr	Same
Distal Tip/ Crossing Profile	1.6Fr, 1.9Fr, 3.2Fr	Same
Shaft Outer Diameter	0.029”, 0.037”, 0.051”	Same
Visibility	Radiopaque catheter body, polymer tip with radiopaque filler	Radiopaque catheter body, polymer tip with increased radiopaque filler
Guidewire Compatibility	0.014”, 0.018”, 0.035”	Same
Sheath / Introducer Compatibility	2.9Fr and 4Fr	Same
Max Infusion Pressure	Tested for manual infusion, not for use with power injectors.	Same
Sterility	Sterile – EO	Same
Biocompatibility	ISO 10993	Same

Functional/Safety Testing:

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

- **Biocompatibility** – Biocompatibility testing was done due to the added hydrophilic coating to the catheter shaft. All tests were done per the same protocol and acceptance criteria as the predicate device, and as prescribed in ISO 10993-1 and 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*
    - *Irritation/ Intracutaneous Toxicity*
    - *Acute Systemic Toxicity*
    - *Material Mediated Pyrogenicity*
    - *Hemolysis Assay*
    - *Complement Activation*
    - *LAL Pyrogenicity*

- **Design Verification** –The XO Cross models all meet or exceeded both Transit Scientifics in-house requirements, and requirements listed in ISO 10555-1.
    - Polymer Tip Extrusion radiopaque filler increase
        - Radiopacity Acceptability
        - Tip ID Testing
        - Tip Tensile Testing
    - Hydrophilic Coating
        - Biocompatibility Testing
        - Catheter OD Testing
        - Coating Lubricity Testing
        - Coating Durability Testing
        - Distal Catheter Tensile
        - Coating Particulate Testing
        - Simulated Use
        - Coating Integrity
        - Coaxial Testing
- **Packaging –** The proposed changes to the XO Cross Support Catheter did not affect the packaging or its configuration.

Conclusion:

The modifications to the subject XO Cross Support catheter is substantially equivalent with respect to safety and effectiveness to the legally marketed predicate device for its intended use. The minor differences between the subject XO Cross Support catheter and the predicated device has no effect on safety or effectiveness, as established through various performance test.