November 29, 2023

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

Re: K231821
Trade/Device Name: XO Cath Microcatheter (E20-090-S, E20-110-S, E20-130-S, E20-150-S, E20-175-S, E20-220-S, E20-090-B, E20-110-B, E20-130-B, E20-150-B, E20-175-B, E20-220-B, E26-090-S, E26-110-S, E26-130-S, E26-150-S, E26-175-S, E26-220-S, E26-090-B, E26-110-B, E26-130-B, E26-150-B, E26-175-B, E26-220-B,)
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: October 27, 2023
Received: October 30, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K231821

Device Name
XO Cath Microcatheter (E20-090-S, E20-110-S, E20-130-S, E20-150-S, E20-175-S, E20-220-S, E20-090-B, E20-110-B, E20-130-B, E20-150-B, E20-175-B, E20-220-B, E26-090-S, E26-110-S, E26-130-S, E26-150-S, E26-175-S, E26-220-S, E26-090-B, E26-110-B, E26-130-B, E26-150-B, E26-175-B, E26-220-B,)

Indications for Use *(Describe)*

The XO Cath Microcatheter is intended for peripheral vascular use. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic or therapeutic materials into the vessel.

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
University of Utah/ Center for Medical Innovation
10 North 1900 East, Rm. 22B
Salt Lake City, UT 84112
(801) 708-2238
Spencer.walker@hsc.utah.edu

Date Prepared: June 20, 2023

Trade Name: XO Cath Microcatheter

Classification Name*:* Continuous Flush Catheter
21 CFR §870.1210, Product Code KRA

Device Class: Class II

Predicate Device: 510(k) No.: K163701
Model: Direxion and Direxion Hi-Flo Torqueable Microcatheter
Manufacture: Boston Scientific Corporation
Classification: KRA

Device Description:
The subject XO Cath Microcatheter is a single-lumen, metal alloy shaft with micro-cuts for flexibility, designed to support a guidewire during access of the peripheral vasculature, and to provide a conduit for the delivery of embolic applications. The XO Cath Microcatheter is available in two lumen sizes, 2.0Fr and 2.6Fr.

The XO Cath 2.0Fr and 2.6Fr Microcatheters are available with a straight or bern tip shape to aid with accessing challenging anatomy. The distal outer surface of the microcatheter is coated with a hydrophilic coating. Radiopaque markers are located at the distal tip to facilitate fluoroscopic visualization. The proximal end incorporates a standard luer for ease of use and to connect with a syringe.

Table 1: XO Cath Microcatheter Model Numbers	
Model No.	**Description**
E20-090-S	XO Cath Microcatheter – 2.0 Fr diameter, and 90cm length, Straight Tip
E20-110-S	XO Cath Microcatheter – 2.0 Fr diameter, and 110cm length, Straight Tip
E20-130-S	XO Cath Microcatheter – 2.0 Fr diameter, and 130cm length, Straight Tip
E20-150-S	XO Cath Microcatheter – 2.0 Fr diameter, and 150cm length, Straight Tip
E20-175-S	XO Cath Microcatheter – 2.0 Fr diameter, and 175cm length, Straight Tip
E20-220-S	XO Cath Microcatheter – 2.0 Fr diameter, and 220cm length, Straight Tip
E20-090-B	XO Cath Microcatheter – 2.0 Fr diameter, and 90cm length, Bern Tip
E20-110-B	XO Cath Microcatheter – 2.0 Fr diameter, and 110cm length, Bern Tip
E20-130-B	XO Cath Microcatheter – 2.0 Fr diameter, and 130cm length, Bern Tip
E20-150-B	XO Cath Microcatheter – 2.0 Fr diameter, and 150cm length, Bern Tip
E20-175-B	XO Cath Microcatheter – 2.0 Fr diameter, and 175cm length, Bern Tip
E20-220-B	XO Cath Microcatheter – 2.0 Fr diameter, and 220cm length, Bern Tip
E26-090-S	XO Cath Microcatheter – 2.6 Fr diameter, and 90cm length, Straight Tip
E26-110-S	XO Cath Microcatheter – 2.6 Fr diameter, and 110cm length, Straight Tip
E26-130-S	XO Cath Microcatheter – 2.6 Fr diameter, and 130cm length, Straight Tip
E26-150-S	XO Cath Microcatheter – 2.6 Fr diameter, and 150cm length, Straight Tip
E26-175-S	XO Cath Microcatheter – 2.6 Fr diameter, and 175cm length, Straight Tip
E26-220-S	XO Cath Microcatheter – 2.6 Fr diameter, and 220cm length, Straight Tip
E26-090-B	XO Cath Microcatheter – 2.6 Fr diameter, and 90cm length, Bern Tip
E26-110-B	XO Cath Microcatheter – 2.6 Fr diameter, and 110cm length, Bern Tip
E26-130-B	XO Cath Microcatheter – 2.6 Fr diameter, and 130cm length, Bern Tip
E26-150-B	XO Cath Microcatheter – 2.6 Fr diameter, and 150cm length, Bern Tip
E26-175-B	XO Cath Microcatheter – 2.6 Fr diameter, and 175cm length, Bern Tip
E26-220-B	XO Cath Microcatheter – 2.6 Fr diameter, and 220cm length, Bern Tip

Indications for Use:

The XO Cath Microcatheter is intended for peripheral vascular use. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic or therapeutic materials into the vessel.

Comparative Analysis:
It has been demonstrated that the XO Cath Microcatheter is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The XO Cath Microcatheter has been fully assessed within the Transit Scientific Risk Management and Design Controls systems. All necessary verification steps met pre-determined acceptance criteria to determine performance as compared to the predicate.

It has been demonstrated that the XO Cath Microcatheter 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 or similar operating principle
- Similar performance specifications
- Similar patient-user interface

Table 2: Substantial Equivalence Comparison Chart

	Subject Device – (*XO Cath 2.0 Fr*)	**Predicate – K163701 (Direxion Microcatheter)**	**Subject Device – (*XO Cath 2.6 Fr*)**	**Predicate – K163701 (Direxion Hi-Flo Microcatheter)**
Ind. for Use	The XO Cath Microcatheter is intended for peripheral vascular use. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.	The Direxion Microcatheters is intended for peripheral vascular use. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.	The XO Cath Microcatheter is intended for peripheral vascular use. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.	The Direxion HI-FLO Torqueable Microcatheters is intended for peripheral vascular use. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.
Classification Name	Cardiovascular Device – Continuous Flush Catheter 21 CFR §870.1210 Product Code: KRA Class II			
Single Use	Yes			
Prescription (Rx Only)	Yes			

Table 2: Substantial Equivalence Comparison Chart				
	Subject Device – (*XO Cath 2.0 Fr)*	**Predicate – K163701 (Direxion Microcatheter)**	**Subject Device – (*XO Cath 2.6 Fr*)**	**Predicate – K163701 (Direxion Hi-Flo Microcatheter)**
Anatomical Access	Peripheral vasculature			
Effective Length (cm)	90cm, 110cm, 130cm, 150cm, 175cm, and 220cm	105cm, 130cm, 155cm	90cm, 110cm, 130cm, 150cm, 175cm, and 220cm	105cm, 130cm, 155cm
Shaft Outer Diameter	Distal: 2.0 Fr Proximal: 2.6 Fr	Distal: 2.4 Fr Proximal: 2.7 Fr	Distal: 2.6 Fr Proximal: 2.75Fr	Distal: 2.8 Fr Proximal: 3.0 Fr
Inner Lumen	0.021”	0.021”	0.027”	0.027”
Max Pressure (PSI)	1200			
Max Flow Rate (mL/s)	2.0Fr x 130cm: 3.0 mL/s	2.4Fr x 130cm: 3.1 mL/s	2.6Fr x 130cm: 5.8 mL/s	2.8Fr x 130cm: 5.6 mL/s
Dead Space Volume (mL)	2.0Fr x 130cm: 0.47 mL	2.4Fr x 130cm: 0.46 mL	2.6Fr x 130cm: 0.66 mL	2.8Fr x 130cm: 0.64 mL
Hydrophilic Coating	Yes			
Visibility/ Radiopacity	Radiopaque Marker Bands on catheter body			
Guidewire Compatibility	Max 0.018”	Max 0.018”	Max 0.021”	Max 0.021”
Guide Catheter Compatibility	Min. 0.038 in	Min. 0.035 in	Min. 0.038 in	Min. 0.038 in
Embolic Compatibility	≤ 700 Micron spheres ≤ 500 Micron particles Coils & Plugs (max 0.021” recommended microcatheter compatible) Liquid Embolics (DMSO, Lipiodol/Ethiodol, Cyanoacrylate adhesives)	≤ 700 Micron spheres ≤ 500 Micron particles Coils (max 0.018" recommended microcatheter compatible) Liquid Embolics (DMSO, Lipiodol/Ethiodol, Cyanoacrylate adhesives, Ethanol)	≤ 900 Micron spheres ≤ 700 Micron particles Coils & Plugs (max 0.027” recommended microcatheter compatible) Liquid Embolics (DMSO, Lipiodol/Ethiodol, Cyanoacrylate adhesives)	≤ 900 Micron spheres ≤ 710 Micron particles Liquid Embolics (DMSO, Lipiodol/Ethiodol, Cyanoacrylate adhesives, Ethanol)
Tip Shape	Straight, Bern	Straight, Bern, J, Swan	Straight, Bern	Straight, Bern, J, Swan
Shapable	No	Some SKUs (via steam)	No	Some SKUs (via steam)

Functional Testing:

The following testing was conducted to validate and verify that the subject device was substantially equivalent to the predicate devices. All data met pre-determined acceptance criteria.

- **Biocompatibility** – Biocompatibility of the complete and finished XO Cath Microcatheter 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.
    - *Cytotoxicity*
    - *Sensitization*
    - *Irritation/ Intracutaneous Toxicity*
    - *Acute Systemic Toxicity*
    - *Material Mediated Pyrogenicity*
    - *Hemolysis Assay*
    - *Complement Activation Assay*
    - *Partial Thromboplastin Time (PTT)*
    - *Blood Platelet and Leukocyte Count Testing*
    - *LAL Pyrogenicity*

- **Design Verification** – Performance bench testing was conducted to ensure that the XO Cath Microcatheter met the applicable design and performance requirements throughout its shelf life, verify conformity to applicable standards, and demonstrate substantial equivalence to the predicate system. The following performance testing was performed or fulfilled with the XO Cath Microcatheter.
    - Material Verification
    - Dimensional Verification
    - Visual Verification
    - Functional/ Simulated Use Testing
    - Static Burst Pressure
    - Maximum Infusion Pressure
    - Maximum Flow Rate
    - Kink Radius
    - Tensile Testing
    - Torque Testing
    - Coating Lubricity
    - Coating Durability
    - Fluid Leak Testing
    - Hub Assembly Air Leak
    - Physical Embolic Testing
    - Liquid Embolic Exposure Testing
    - Radiopacity
    - Packaging
    - Sterilization

Conclusion:
Based on the similarities in design between the subject and predicate devices, and the performance testing performed, the subject XO Cath Microcatheter is substantially equivalent to the cited predicate device.