June 17, 2024

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: K232258
Trade/Device Name: XO Constrain™ Percutaneous Transluminal Angioplasty Constraining Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: PNO
Dated: May 28, 2024
Received: June 3, 2024

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2024.06.17 15:38:24 -04'00'

for Gregory O'Connell
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232258

Device Name
XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter

Indications for Use *(Describe)*
The XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter is intended to be used in conjunction with a PTA balloon to facilitate dilation and apposition of the scoring/constraining surface to the stenotic material in the iliac, femoral, ilio-popliteal, infra-popliteal, and renal arteries, and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

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: May 31, 2024

Trade Name: XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter

Classification Name: Percutaneous Scoring Catheter
21 CFR §870.1250, Product Code PNO

Device Class: Class II

Predicate Device: 510(k) No.: K221986
Model: XO Score LP Percutaneous Transluminal Angioplasty Scoring Catheter
Manufacture: Transit Scientific, LLC
Classification: PNO

Reference Device: 510(k) No.: K150634
Model: AngioSculpt PTA Scoring Balloon Catheter
Manufacture: Spectranetics Co.
Classification: PNO

Device Description:
The XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter is a balloon dilation scoring/constraining catheter. It consists of a metal alloy wire shaft connected to the metal alloy expandable constraining structure (CS) at the distal atraumatic tapered tip. It works with off-the-shelf compliant and semi-compliant balloons to expand the constraining structure and is designed to facilitate uniform, atraumatic balloon expansion, vessel scoring, and rewrap within small or distal vessels and arteries. The XO Constrain catheter is designed to be used with balloons between the sizes of 6 - 20mm in length and 1.5 – 4.0mm in diameter and may work with

PTA and peripheral use PTCA balloon catheters with a standard over-the-wire (OTW) or rapid exchange (RX) procedural approaches. The expansion of the CS is determined by the balloon inflation diameter. Upon deflation the CS returns to its original shape and is removed from the vessel along with the balloon catheter. The XO Constrain should not be used in the coronary or neuro-vasculature.

Indications for Use:

The XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter is intended to be used in conjunction with a PTA balloon to facilitate dilation and apposition of the scoring/constraining surface to the stenotic material in the iliac, femoral, ilio-popliteal, infra-popliteal, and renal arteries, and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Comparative Analysis:
It has been demonstrated that the XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter is comparable to the predicate device in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The XO Constrain 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 safety and effectiveness.

It has been demonstrated that the XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter is comparable to the predicate device in the following manner:

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

Table 1: Substantial Equivalence Comparison Chart			
	Subject Device – (*XO Constrain Catheter)*	**Predicate – K221986 (XO Score LP Catheter)**	**Reference – K150634 – (AngioSculpt PTA Catheter)**
Ind. for Use	The XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter is intended to be used in conjunction with a PTA balloon to facilitate dilation and apposition of the scoring/constraining surface to the stenotic material in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries,	The XO Score LP Percutaneous Transluminal Angioplasty Scoring Catheter is intended to be used in conjunction with a PTA balloon to facilitate dilation and apposition of the scoring surface to the stenotic material in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for treatment of obstructive lesions of native or	For dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Table 1: Substantial Equivalence Comparison Chart			
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	and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.	synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.	
Anatomical Access	Peripheral Vasculature	Peripheral Vasculature	Peripheral Vasculature
Shaft Construction	Wire with Polymer Covering	Wire with Polymer Covering	Two-Lumen Polymer Shaft
Constraining/ Scoring Structure	Metal Alloy Hypotube	Metal Alloy Hypotube	3-5 Wires
Effective Length (cm)	145cm	150 cm	50 cm, 90 cm, 137 cm
Crossing Profile	Distal tip: 1.5Fr	2.2Fr distal tip: 1.5Fr 3.8Fr distal tip: 1.9Fr	.014” GW Compatible: 1.5F .018” GW Compatible: 1.9F
Balloon Diameter	Compatible with 1.5mm – 4.0mm compliant and semi-compliant balloons	2.2Fr: 1.5 – 4.0mm 3.8Fr: 3 - 7mm	2-8 mm
Balloon Length	Compatible with 6mm - 20mm compliant and semi-compliant balloons	Compatible with PTA balloon lengths of 20-200 mm	10 mm – 200 mm
Constraining Structure (Inflated Diameter)	1.7mm – 4.2mm max	2.2Fr: 1.8 – 4.3mm 3.8Fr: 3.4 – 7.4 mm	2-8 mm (balloon profile only)
Visibility/ Radiopacity	The catheter tip and the scoring/constraining structure are radiopaque. The balloon catheter marker bands are visible through the constraining structure when inflated.	The catheter tip and the scoring structure are radiopaque. The balloon catheter marker bands are visible through the constraining structure when inflated.	The balloon catheter has two marker bands are visible through the balloon material.
Guidewire Compatibility	Max 0.014”	2.2Fr: Max 0.014” 3.8Fr: Max 0.018”	Max 0.018”

Functional/Safety 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 Constrain 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.

- Cytotoxicity
- Sensitization
- Irritation/ Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemolysis Assay
- Complement Activation Assay
- Partial Thromboplastin Time (PTT) Assay
- Heparinized Blood Platelet and Leukocyte Count Assay
- LAL Bacterial Endotoxin Pyrogenicity

Design Verification – Performance bench testing was conducted to ensure that the XO Constrain Catheter 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 Constrain Catheter.

- Material Verification
- Dimensional Verification
- Visual Verification
- Functional/ Simulated Use Testing
- PTA/PTCA Cycling
- Rewrap/ Recovery
- Retrieval Force
- PTA/PTCA Burst Pressure
- Torque Testing
- Kink Radius
- Tensile Testing
- Particulate Testing
- Corrosion Testing
- Packaging
- Sterilization
- Finite Element Analysis (FEA)

Animal Testing: Animal testing was conducted to assess the safety, usability, and scoring performance of the subject device.

Conclusion:
The XO Constrain Percutaneous Transluminal Angioplasty Constraining Catheter is substantially equivalent to the cited predicate device and met all acceptance criteria.