October 18, 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: K221986
Trade/Device Name: XO Score LP Percutaneous Transluminal Angioplasty Scoring Catheter, XO Score LP Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: September 29, 2022
Received: September 29, 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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K221986

Device Name

XO SCORE LP Percutaneous Transluminal Angioplasty Scoring Catheter, XO Score LP Catheter

Indications for Use *(Describe)*

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 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:** October 5, 2022

**Trade Name:** XO Score LP Percutaneous Transluminal Angioplasty Scoring Catheter
XO Score LP Catheter

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

**Device Class:** Class II

**Predicate Device:** 510(k) No.: K193495
Model: XO Score Percutaneous Transluminal Angioplasty Scoring Catheter
Manufacture: Transit Scientific, LLC
Classification: PNO

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

**Device Description:**
The XO Score LP (Low Profile) Percutaneous Transluminal Angioplasty Scoring Catheter is a 2.2 Fr (0.76 mm) and 3.8 Fr (1.27 mm) diameter, single-lumen, metal alloy shaft, a proximal polymer outer jacket and a balloon expandable scoring element at the distal tip. Designed to work with a standard PTA balloon catheter. The XO Score LP catheter essentially adds the lesion scoring / cutting capability to a standard PTA balloon catheter with the scoring element at

its distal end. It is available in the one catheter length (150 cm), and longitudinal scoring element length (23cm).

| Table 1: XO Score LP Catheter Model Numbers | | |
|---|---|---|
| **Product Family** | **Model No.** | **Description** |
| XO Score LP Catheter | S3.20-150 | *XO Score LP Catheter* – 2.2 Fr (0.76 mm) and 3.8 Fr (1.27 mm) diameter catheter shaft in 150cm lengths. |
| | S2.15-150 | |

**Indications for Use:**
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 synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

**Comparative Analysis:**
Modifications in design, materials, and size range to the previously 510(k) cleared XO Score Catheter (K193495) resulted in new product codes. The following modifications were made to the subject catheter:

- Catheter Shaft Design
- Catheter Sizes (Diameter)
- Catheter Effective Length
- Number of Scoring Struts
- Scoring Element Diameter when Expanded
- Scoring Depth
- Balloon Length Compatibility
- Tip Material
- Accessory Loading Tool

It has been demonstrated that the modified XO Score LP 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 Score LP 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 – K193495 (XO Score Catheter)** | **Subject Device – (XO Score LP Catheter)** |
| **Ind. for Use** | The XO Score 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 synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature. | 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 synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature. |
| **Classification Name** | Cardiovascular Device – Percutaneous Catheter<br>21 CFR §870.1250<br>Product Code: PNO<br>Class II | Same |
| **Single Use** | Yes | Same |
| **Fundamental Scientific Technology** | Dilation and treatment of obstructive lesions | Same |
| **Prescription (Rx Only)** | Yes | Same |
| **Anatomical Access** | The iliac, femoral, ilio-femoral, popliteal, infra-popliteal, renal arteries and arteriovenous dialysis fistulae | Same |
| **Effective Length (cm)** | 65 cm, 125 cm | 150 cm |
| **Shaft Outer Diameter** | 6.4Fr (0.085”) | D15: 2.2 Fr (0.030”)<br>D20: 3.8 Fr (0.050”) |
| **Scoring Length(s)** | 5cm, 7cm, 11.5cm, 13.5cm | 23 cm |
| **PTA Balloon Length** | Compatible with PTA balloon lengths of 20-40 mm | Compatible with PTA balloon lengths of 20-200 mm |
| **Scoring Members** | D25: 22 Struts,<br>D35: 14 Struts,<br>D50: 14 Struts | D15: 10 Struts<br>D20: 12 Struts |
| **Expanded Scoring Element Diameter** | D25: 4.5 - 8.5 mm<br>D35: 4.7 - 8.7 mm<br>D50: 5 - 9 mm | D15: 1.8 – 4.3 mm<br>D20: 3.4 – 7.4 mm |
| **Scoring Depth** | D25: 0.25 mm scoring depth<br>D35: 0.35 mm scoring depth<br>D50: 0.50 mm scoring depth | D15: 0.15 mm scoring depth<br>D20: 0.20 mm scoring depth |
| **Integrated Balloon** | No | No |

| Table 2: Substantial Equivalence Comparison Chart | | |
|---|---|---|
| | **Predicate – K193495 (XO Score Catheter)** | **Subject Device – (XO Score LP Catheter)** |
| **Scoring member fixed to Balloon** | No | No |
| **Scoring member Profile (Design)** | Rectangular Edges/ Diamond Pattern | Same |
| **Scoring member size (thickness)** | 0.0025” | D15: 0.0025”<br>D20: 0.0030” |
| **Rated Burst Pressure** | Dependent on RBP of Balloon Used | Same |
| **Visibility** | Radiopaque catheter body and tip | Radiopaque catheter body, polymer tip with radiopaque filler |
| **Guidewire Compatibility** | 0.014”, 0.018”, 0.035” | D15: 0.014”<br>D20: 0.014”, 0.018” |
| **Sheath / Introducer Compatibility** | 1 French Size Larger than the PTA labeling | 1 French Size Larger than the PTA labeling |
| **Sterility** | Sterile – EO | Same |
| **Biocompatibility** | ISO 10993 | Same |

**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 Score LP* 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.
    - Additional material biocompatibility data was leveraged from the K193420 reference device, to support the modified subject device since the device materials and manufacturing processes are the same.
    - Cytotoxicity testing was completed for the Accessory Loading Tool.
- **Design Verification** – Performance bench testing was conducted to ensure that the XO Score LP 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 Score LP Catheter.

  - Kink Radius
  - Tensile Testing
  - Retrieval Force Testing
  - Device Recovery
  - Accessory PTA Balloon Catheter burst pressure within XO Score LP Catheter
  - Torque
  - XO Score LP Catheter Cycling with Accessory PTA Balloon catheter
  - Scoring Capability Assessment
- **Packaging –** The proposed changes to the XO Score LP Catheter did not affect the packaging or its configuration.
- **Sterilization** - The proposed changes to the XO Score LP Catheter did not affect the sterilization cycle or its parameters.

**Conclusion**:
The minor differences between the subject XO Score LP catheter and the predicated device did not raise new questions of safety or effectiveness during the design verification testing. The subject device is substantially equivalent to the predicate device.