May 29, 2020

Transit Scientific
Ms. Srividya Pothana
Regulatory Affairs Specialist
University of Utah
10 North 1900 East, EHSL Rm. 22B
Salt Lake City, Utah 84112

Re: K193495
Trade/Device Name: XO Score Percutaneous Transluminal Angioplasty Scoring Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: April 29, 2020
Received: April 30, 2020

Dear Ms. Pothana:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193495

Device Name
XO Score Percutaneous Transluminal Angioplasty Scoring Catheter

Indications for Use *(Describe)*
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.

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: Srividya Pothana, MS – Regulatory Affairs Specialist
Center for Medical Innovation
10 North 1900 East, Rm 22B
Salt Lake City, UT 84112
(801) 587-1456

Date Prepared: December 27, 2019

Trade Name: XO Score Percutaneous Transluminal Angioplasty Scoring Catheter

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

Device Class: Class II

Predicate Device:

- K150634 – AngioSculpt PTA Scoring Catheter - Spectranetics Corporation
- K113103 – Splitwire Percutaneous Transluminal Angioplasty Scoring Device - Rex Medical

Device Description:

The XO Score Percutaneous Transluminal Angioplasty Scoring Catheter is a 6.3 Fr (2.08 mm) diameter, single-lumen, metal alloy hypotube 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 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 various catheter lengths (65cm, 125cm), and longitudinal scoring element lengths (5cm, and 7cm).

Indications 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.

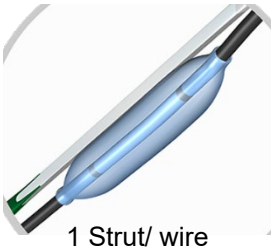
Comparative Analysis:
It has been demonstrated that the XO Score catheter is comparable to the predicate devices in intended use, fundamental scientific technology, design, principles of operation and functional performance evaluations. The XO Score catheter has been fully assessed within the Transit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

It has been demonstrated that the XO Score catheter is comparable to the predicate devices in the following manner:

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

Table 11-2: Substantial Equivalence Comparison Chart

	Predicate – K150634 AngioSculpt PTA Scoring Balloon Catheter	**Predicate – K113103 SplitWire PTA Scoring Catheter**	**Subject Device – XO Score PTA Scoring Catheter**
Ind. for Use	The AngioSculpt PTA Scoring Balloon Catheter is intended for dilation of lesions 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 SplitWire Percutaneous Transluminal Angioplasty Scoring device is indicated for the use with PTA balloon to facilitate dilation of stenosis 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.	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.
Classification Name	Cardiovascular Device – Percutaneous Catheter 21 CFR §870.1250 Product Code: PNO Class II	Same	Same
Fundamental Scientific Technology	Dilation and treatment of obstructive lesions	Same	Same
Single Use	Yes	Same	Same

Table 11-2: Substantial Equivalence Comparison Chart			
	Predicate – K150634 AngioSculpt PTA Scoring Balloon Catheter	**Predicate – K113103 SplitWire PTA Scoring Catheter**	**Subject Device – XO Score PTA Scoring Catheter**
Prescription (Rx Only)	Yes	Same	Same
Anatomical Access	The iliac, femoral, ilio-femoral, popliteal, infra-popliteal, renal arteries and arteriovenous dialysis fistulae	Same	Same
Where used	Hospitals and Clinics	Same	Same
Effective Length	50 cm, 90 cm, 137 cm	90 cm,180 cm, 260 cm	65 cm, 125 cm
Balloon Length	10 mm – 200 mm	Compatible with balloon lengths of 20-80 mm	Compatible with balloon lengths of 20-40 mm
Expanded Scoring Element Diameter	2-8 mm (balloon)	Unlimited	S6.25: 4.5 - 8.5 mm S6.35: 4.7 - 8.7 mm S6.50: 5 - 9 mm
Integrated Balloon	Yes	No	No
Scoring member fixed to Balloon	No	No	No
Scoring Members	 3-5 Struts	 1 Strut/ wire	 S6.25: 22 Struts, S6.35: 14 Struts, S6.50: 14 Struts
Scoring member Profile (Design)	Rectangular Edges/ Helical Pattern	Triangular Wedge, Straight Pattern	Rectangular Edges/ Diamond Pattern
Scoring member size (thickness)	~.008”-.010”	0.014”	0.0025”
Rated Burst Pressure	2-20 atm	Dependent on RBP of Balloon Used	Dependent on RBP of Balloon Used
Visibility	Radiopaque Markers	2 Radiopaque Markers	Radiopaque catheter body and tip
Guidewire Compatibility	0.018”	0.035” or 0.018”	0.014”, 0.018”, 0.035”
Sheath / Introducer Compatibility	5 – 6 Fr	Dependent on the introducer compatibility of the balloon used	7 Fr
Sterility	EO Sterile	Same	Same
Biocompatibility	ISO 10993	Same	Same

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.

- **Design Verification** –The XO Score catheter meet or exceeded both Transit Scientific's in-house requirements, and requirements listed in ISO 10555-1. Packaging integrity was validated in conjunction with the sterilization studies.

- **Biocompatibility** – Biocompatibility of the complete and finished *XO Score* 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. Per ISO 10993-1, testing included the following:
  - Cytotoxicity
  - Irritation/ Intracutaneous Toxicity
  - Sensitization
  - Systemic Injection
  - Material Mediated Pyrogenicity
  - Hemolysis Complete
  - Complement Activation
  - Thrombogenicity

- **Preclinical Data:**
  An animal study (Ovine model) was done as a comparative study to demonstrate and compare the functionality, safety, and performance of the subject XO Score catheter to the predicate device. The results of the study demonstrated that the subject XO Score catheter is at least equivalent to the predicate catheter in the areas of functionality, safety, and performance.

Conclusion:
Based on the similarities in design between the subject and predicate devices, and the performance testing performed, the subject XO Score catheter is substantially equivalent to the cited predicate devices. Additionally, the XO Score catheter met all acceptance criteria to support substantial equivalence.