OrbusNeich Medical Trading, Inc.
John Pazienza
General Manager and Senior Director, Engineering
5363 NW 35th Avenue
Fort Lauderdale, FL 33309

Re: K182713
Trade/Device Name: Scoreflex PTA Scoring Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: May 6, 2019
Received: May 7, 2019

Dear Mr. Pazienza:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Plaque Modification Devices Team
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)*

K182713

Device Name
Scoreflex PTA Scoring Balloon Catheter

Indications for Use *(Describe)*

The Scoreflex PTA Scoring Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral 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

This 510(k) Summary is submitted in accordance with 21 CFR 807.92(c).

Submitter:	OrbusNeich Medical Trading, Inc. 5363 NW 35th Avenue Fort Lauderdale, FL 33309 Phone: 954.730.0711 Fax: 954.730.7601
Contact Person:	John D. Pazienza
Date Prepared:	November 15, 2018
Trade Name:	Scoreflex PTA Scoring Balloon Catheter
Common Name:	Scoring Balloon Catheter
Classification Name:	Catheter, Percutaneous, Cutting/Scoring 21 CFR 870.1250
Product Code:	PNO
Device Class:	Class II
Predicate Device:	Bard Vascutrak (K103459; PNO; cleared December 13, 2010)
Reference Devices:	Angioscore, Inc. Angiosculpt (K142983; cleared March 4, 2015) OrbusNeich Jade (K173894; cleared February 9, 2018)
Device Description:	The Scoreflex PTA Scoring Balloon Catheter is designed for easy guidewire exchange and available with balloon diameters of 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, and 6.0mm, balloon lengths of 15, 20 and 40mm and a catheter working length of 40, 90, or 150cm. There are two catheter designs within the Scoreflex family: the no-coil design has a smaller shaft profile than the corresponding coil design catheter of the same balloon configuration which will allow for access to more distal lesions while the coil design minimizes balloon curvature during inflation. The balloon is made of a semi-complaint material with a rated burst pressure of 14 atmospheres. The proximal shaft of the catheter is composed of a female luer connector bonded to a nylon jacketed stainless steel hypotube and the scoring wire is laser welded to the distal end of the hypotube. The proximal shaft joins with a smooth transition to the distal shaft (composed of an outer nylon tube with the balloon/tip tube and scoring wire welded at the distal tip). The cutting section of the scoring wire is outside of the balloon. Two radiopaque platinum/iridium marker bands are located on the scoring wire and aligned with the balloon shoulders to ensure accurate positioning of the balloon. The tip lumen is compatible with either a standard 0.014 inch (0.36mm) or 0.018 inch (0.46mm) guidewire. The guidewire enters the catheter tip and advances coaxially out the Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guidewire. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements. The catheter is lubricated with hydrophilic coating on the tip and the distal outer body surface; the tip lumen and the balloon are lubricated with silicone coating.

Intended Use:	The Scoreflex PTA Scoring Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature.
Technological Characteristics:	At a high level, the subject and predicate devices are based on the same technological elements: • similar indications for use • rapid exchange catheter design • semi-compliant balloon • scoring wire design • hydrophilic coating • 0.014" and 0.018" guidewire compatibility • EO sterilization The following technological differences exist between the subject and predicate device: • specific materials selected • exact dimensions of components and catheter • catheter working length • balloon diameter and length range • nominal and rated burst pressure
Performance Data:	Testing was performed to support the use of the Scoreflex PTA Scoring Balloon Catheter: • Sterilization • Shelf-Life • Performance Testing o Visual Inspection o Dimension Inspection o Balloon Preparation, Deployment, and Retraction o Balloon Rated Burst Pressure o Shaft Burst o Balloon Fatigue o Balloon Compliance o Balloon Inflation and Deflation Time o Catheter Bond Strength o Tip Pull Strength o Flexibility and Kinking o Torque Strength o Radiopacity o Coating Integrity o Particulate Evaluation o Balloon Rated Burst Pressure (within stent) o Balloon Fatigue (within stent) • Biocompatibility o Cytotoxicity o Sensitization o Intracutaneous Reactivity o Acute Systemic Toxicity o Hemocompatibility ▪ Hemolysis ▪ Partial Thromboplastin Time

- Platelet and Leukocyte Counts
- Complement Activation
- *In vivo* Thromboresistance

- Pyrogenicity
- Genotoxicity

The Scoreflex PTA Scoring Balloon Catheter test results met all acceptance criteria and were similar to the predicate and reference devices.

Conclusion: This information supports a determination of substantial equivalence between the Scoreflex PTA Scoring Balloon Catheter and the predicate device described above.