March 04, 2020

OrbusNeich Medical Trading Inc.
John Pazienza
Senior Director, Engineering
5363 NW 35th Avenue
Fort Lauderdale, Florida 33309

Re: K200269
Trade/Device Name: Sapphire II PRO Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (Ptca) Catheter
Regulatory Class: Class II
Product Code: LOX, LIT
Dated: January 31, 2020
Received: February 4, 2020

Dear Mr. John 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/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)*
K200269

Device Name
Sapphire II PRO Balloon Dilatation Catheter

Indications for Use *(Describe)*

The Sapphire® II PRO balloon dilatation catheter (1.0-1.25mm configurations) is indicated for:
• balloon pre-dilatation of a stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of improving myocardial perfusion.

The Sapphire® II PRO balloon dilatation catheter (1.5-4.0mm configurations) is indicated for:
• balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.
• balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction.

The Sapphire® II PRO balloon dilatation catheter is also indicated for:
• percutaneous transluminal angioplasty in the peripheral vasculature, including renal, femoral, popliteal, infra-popliteal, tibial, and peroneal arteries.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	January 31, 2020
Trade Name:	Sapphire II PRO Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheters, transluminal coronary angioplasty, percutaneous 21 CFR 870.5100(a)
Product Code:	LOX (primary) LIT (secondary
Device Class:	Class II
Predicate Device:	OrbusNeich Sapphire II PRO (K180921; LOX, LIT; cleared 28-Jun-2018)
Reference Devices:	Abbott Vascular Mini Trek OTW (K110617; LOX; cleared 02-Jun-2011) Boston Scientific Emerge OTW (K130391; LOX; cleared 10-Jul-2013) Medtronic Sprinter Legend OTW (K103095; LOX; cleared 22-Oct-2010)
Device Description:	The Sapphire II PRO Balloon Dilatation Catheter is now also available as an over-the-wire balloon catheter with a working length of 150cm. The semi-compliant balloons are available in diameters from 1.0-1.25mm and lengths from 5-15mm with a rated burst pressure of 14 atmospheres. The catheter consists of proximal section with a Y-type hub and distal section with a balloon near the distal tip. The straight port of the hub is the guidewire entrance and the side port is used to inflate and deflate the balloon. The external lumen provides for inflation of the balloon with dilute contrast media solution. The internal lumen permits the use of a standard 0.014 inch guidewire to facilitate advancement of the catheter to and through the stenosis to be dilated. Hydrophilic lubricious coatings are applied to the distal section. One radiopaque platinum marker band is located within the balloon segment. The catheter is compatible with 5F or larger guiding catheters and 4F or larger guiding sheaths. Two marked sections (3mm in length) are located on the proximal shaft to indicate catheter position relative to the tip of either guiding catheter or guiding sheath. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

Intended Use:	The Sapphire® II PRO Balloon Dilatation Catheter (∅1.0-1.25mm configurations) is indicated for: • balloon pre-dilatation of a stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis) for the purpose of improving myocardial perfusion The Sapphire® II PRO Balloon Dilatation Catheter (∅1.5-4.0mm configurations) is indicated for: • balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion • balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction The Sapphire® II PRO Balloon Dilatation Catheter is also indicated for: • percutaneous transluminal angioplasty in the peripheral vasculature, including renal, femoral, popliteal, infra-popliteal, tibial, and peroneal arteries.
Technological Characteristics:	At a high level, the subject and predicate devices are based on the same technological elements: • the same indications for use • identical semi-compliant balloon • nominal pressure of 6 atm • rated burst pressure of 14 atm • identical distal shaft • hydrophilic coating • 0.014” guidewire compatibility • EO sterilization The following technological differences exist between the subject and predicate device: • over-the-wire catheter shaft design • specific materials selected for proximal shaft • exact dimensions of proximal shaft components and catheter

Performance Data:

Testing was leveraged from the predicate device (K180921) when applicable:

- Shelf-Life (Partial)
- Performance Testing (Partial)
  - Dimensional Verification (Partial)
  - Balloon Rated Burst Pressure (Partial)
  - Balloon Fatigue
  - Balloon Compliance
  - Catheter Bond Strength (Partial)
  - Tip Pull Strength
  - Radiopacity
  - Coating Integrity

Additional testing was performed to support the use of the Sapphire II PRO balloon dilatation catheter over-the-wire shaft design:

- Sterilization
- Performance Testing
  - Visual Inspection
  - Dimensional Verification
  - Balloon Preparation, Deployment, and Retraction
  - Balloon Rated Burst Pressure
  - Shaft Burst
  - Balloon Inflation and Deflation Time
  - Catheter Bond Strength
  - Flexibility and Kinking
  - Torque Strength
  - Particulate Evaluation
- Biocompatibility
  - Cytotoxicity
  - Intracutaneous Reactivity
  - Sensitization
  - Acute Systemic Toxicity
  - Pyrogenicity
  - Hemocompatibility
    - Hemolysis
    - Complement Activation
    - Partial Thromboplastin Time
    - Platelet and Leukocyte Counts
  - Genotoxicity

The Sapphire II PRO balloon dilatation catheter test results met all acceptance criteria and were similar to the predicate device.

Conclusion:

This information supports a determination of substantial equivalence between the Sapphire II PRO balloon dilatation catheter and the predicate device described above.