June 28, 2018

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

Re: K180921
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: April 6, 2018
Received: April 9, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

Gregory O'Connell
2018.06.28 13:35:53 -04'00'

For

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K180921

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 purposes 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.

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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:	June 22, 2018
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:	Bard Ultraverse (K131199; LIT; cleared May 30, 2013)
Reference Devices:	Abbott Armada 14 XT (K121352; LIT; cleared 15-Aug-2012) Brosmed Castor NC (K160941; LIT; cleared 13-Dec-2016) OrbusNeich Jade (K173894; LIT; cleared 9-Feb-2018) OrbusNeich Sapphire II PRO (K173680; LOX; cleared 1-Mar-2018) OrbusNeich Sapphire II PRO (K163114; LOX; cleared 5-Jan-2017)
Device Description:	The Sapphire II PRO balloon dilatation catheter is a rapid exchange balloon catheter with a working length of 140cm design for both coronary and peripheral indications. This catheter was previously cleared for coronary use (K173680, K163114) and this submission is intended to support the peripheral use of this balloon catheter. The proximal shaft is a PTFE coated stainless steel hypotube. Hydrophilic lubricious coatings are applied to the distal section. The semi-compliant balloons, available in diameters from 1.0-4.0mm and lengths from 5-30mm, can be inflated by injecting dilute contrast media solution through the trailing hub of the catheter. Two radiopaque platinum marker bands are located within the balloon segment (there is only one centrally located marker band for the ∅1.0-1.5mm configurations). The catheter is compatible with 4F or larger guiding sheaths or 5F or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014 inch guidewire. The proximal part of the guidewire enters the catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with a single standard length guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position relative to the tip of either a guiding sheath or guiding catheter. 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 purposes 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
- rapid exchange catheter design
- hydrophilic coating
- semi-compliant balloon
- nominal pressure of 6 atm
- 0.014" guidewire compatibility
- EO sterilization

The following technological differences exist between the subject and predicate device:

- specific materials selected
- exact dimensions of components and catheter
- balloon diameter and length range
- rated burst pressure of 14 atm (vs. 16 atm)

Performance Data:

Testing was leveraged from the reference device (K173680, K163114):

- Sterilization (Complete)
- Shelf-Life (Complete)
- Performance Testing (Partial)
  - Dimensional Verification
  - Balloon Rated Burst Pressure
  - Shaft Burst
  - Balloon Fatigue
  - Balloon Compliance
  - Balloon Inflation and Deflation Time
  - Catheter Bond Strength
  - Tip Pull Strength
  - Flexibility and Kinking
  - Torque Strength
  - Radiopacity
  - Coating Integrity
  - Particulate Evaluation

Additional testing was performed to support the peripheral use of the Sapphire II PRO balloon dilatation catheter:

- Performance Testing
  - Visual Inspection
  - Balloon Preparation, Deployment, and Retraction

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

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