August 16, 2024

OrbusNeich Medical (Shenzhen) Co., Ltd.
Jerry Cheung
Senior Director of Regulatory Affairs
No.1 Jinkui Road
Futian Free Trade Zone
Shenzhen, 518038
China

Re: K233499
Trade/Device Name: Sapphire NC ULTRA Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: July 16, 2024
Received: July 16, 2024

Dear Jerry Cheung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Brian D. Pullin -S

for Lydia Glaw
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.

Submission Number *(if known)*

K233499

Device Name

Sapphire NC ULTRA Coronary Dilatation Catheter

Indications for Use *(Describe)*

The Sapphire NC ULTRA Coronary Dilatation Catheter 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.
- · In-stent restenosis.
- · Post-delivery expansion of balloon expandable coronary stents.

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.

Submitter:	OrbusNeich Medical (Shenzhen) Co., Ltd. No.1 Jinkui Road Futian Free Trade Zone Shenzhen 518038, China Phone: +86-755-83580181 Fax: +86-755-83580169
Contact Person:	Name: Jerry Cheung Job Title: Senior Director of Regulatory Affairs Email: jcheung@orbusneich.com
Date Prepared:	October 30, 2023
Device:	Device Name: Sapphire NC ULTRA Coronary Dilatation Catheter Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter Trade Name: Sapphire NC ULTRA Regulation Number: 21 CFR 870.5100(a) Regulatory Class: II Product Code: LOX
Predicate Device:	Sapphire NC 24 Coronary Dilatation Catheter (K211807, LOX; cleared Oct.14, 2021) This predicate has not been subject to a design-related recall.
Reference Devices:	Sapphire NC Plus Coronary Dilatation Catheter (K162209; cleared Oct.06, 2016) (K192344; cleared Sep.19, 2019) Sapphire II Pro Coronary Dilatation Catheter (K163114; cleared Jan.05, 2017) (K173680; cleared Mar.1, 2018)
Device Description:	The Sapphire NC ULTRA Coronary Dilatation Catheter is designed to allow easy exchange of the catheter using a standard length 0.014 inch guidewire. Balloon diameters range from 1.75mm to 5.0mm. The balloon material is made of a minimally compliant material, 1.75mm to 4.0mm balloons have a rated burst pressure of 20 atmospheres, and 4.5mm to 5.0mm balloons have a rated burst pressure of 18

atmospheres. The minimally compliant balloon material allows high pressure dilatation while maintaining precise control of the balloon diameter and length. The proximal shaft of the catheter is composed of a female luer connector connected to a PTFE coated stainless steel tube. The proximal shaft allows superior proximal pushability and trackability with a smooth transition to a distal shaft. Two radiopaque platinum/iridium marker bands are located within the balloon segment. The guidewire enters the catheter tip and advances coaxially out the distal Rx port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard-length guidewire. Two marked sections of 5mm length each located on the proximal shaft indicate catheter position relative to the tip of either a brachial or femoral guiding catheter.

Indications for Use:

The indications for use for Sapphire NC ULTRA Coronary Dilatation Catheter remain the same as the predicate device (Sapphire NC 24):

The Sapphire NC ULTRA Coronary Dilatation Catheter 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
- In-stent restenosis
- Post-delivery expansion of balloon expandable coronary stents

Technological Characteristics:

The subject device has the following similarities to the predicate devices:

- Same indications for use
- Same catheter design
- Same sterilization method

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

- Materials of construction
- Performance specifications
- Shelf life

Performance Data:

The following performance data were provided in support

of the substantial equivalence determination.

- In vitro performance tests were conducted on subject device in accordance with FDA guidance "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters" issued on September 8, 2010, including:
  - Visual Inspection
  - Particulate Evaluation
  - Dimensional Verification
  - Balloon Compliance
  - Hub leakage test
  - Balloon Preparation, Deployment, and Retraction
  - Balloon Inflation and Deflation Time
  - Coating Integrity
  - Balloon Fatigue (in-stent)
  - Balloon Fatigue
  - Balloon Rated Burst Pressure (in-stent)
  - Balloon Rated Burst Pressure
  - Shaft burst
  - Catheter Bond Strength
  - Tip Pull Strength
  - Flexibility and Kink
  - Torque Strength
  - Marker Band Radiopacity

- Biocompatibility testing, conducted in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a Risk Management Process" issued on June 16, 2016, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA, included:
  - Cytotoxicity
  - Sensitization
  - Intracutaneous reactivity
  - Acute systemic toxicity
  - Pyrogenicity
  - Hemocompatibility
    - Hemolysis
    - Partial thromboplastin time
    - Platelet and leukocyte counts

- Complement activation
- Toxicological Risk Assessment (TRA) of Extractable Chemicals

- Packaging and sterilization validation

- Shelf life

The test results met all acceptance criteria, which are the same or similar to the predicate device and ensure that the Sapphire NC ULTRA Coronary Dilatation Catheter design and construction are suitable for their intended use.

Conclusion: This information supports a determination of substantial equivalence between the subject device and the predicate device described above.