October 14, 2021

OrbusNeich Medical (Shenzhen) Co., Ltd.
Daniel Zhang
Director of Regulatory Affairs and Quality
No.1 Jinkui Road, Futian Free Trade Zone
Shenzhen, Guangdong 518038
China

Re: K211807
Trade/Device Name: Sapphire NC 24 Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX

Dear Daniel Zhang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 14, 2021. Specifically, FDA is updating this SE Letter due to a missing digital signature as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, 301-796-6075, Gregory.oconnell@fda.hhs.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.10.14 09:09:58 -04'00'

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

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Regulation Number: 21 CFR 870.5100
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Regulatory Class: Class II
Product Code: LOX
Dated: September 9, 2021
Received: September 15, 2021

Dear Daniel Zhang:

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,

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K211807

Device Name
Sapphire NC 24 Coronary Dilatation Catheter

Indications for Use *(Describe)*
The Sapphire NC 24 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."*

**K211807**

**510(k) Summary**

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

**Submitter Information:**

| | |
|---|---|
| 510(k) Submitter: | OrbusNeich Medical (Shenzhen) Co., Ltd.<br>No.1 Jinkui Road, Futian Free Trade Zone<br>Shenzhen, Guangdong, 518038, China<br>Phone: +86-755-83580181<br>Fax: +86-755-83580169 |
| Contact person: | Daniel Zhang<br>Phone: +86-755-83580181-8302<br>Fax: +86-755-83580169 |
| Submission date: | May 30, 2021 |

**Subject Device Information:**

| | |
|---|---|
| Device name: | Sapphire NC 24 Coronary Dilatation Catheter |
| Regulation name | Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter |
| Trade or propriety name | Sapphire NC 24 |
| Regulation Number: | 21 CFR 870.5100(a) |
| Panel Code: | Cardiovascular |
| Classification: | Class II |
| Product Code: | LOX |

**Predicate Device:**

Sapphire NC Plus Coronary Dilatation Catheter
(K162209; cleared October 6, 2016)
(K192344; cleared September 19, 2019)

Reference Device:

Sapphire II Pro Coronary Dilatation Catheter
(K163114; cleared January 05, 2017)
(K173680; cleared March 1, 2018)

**Device Description:**

The Sapphire NC 24 Coronary Dilatation Catheter is designed to allow easy exchange of the catheter using a standard length 0.014 inch guidewire. Balloon diameters range from 1.5mm to 5.0mm. The balloon material is made of a minimally compliant material, 1.5mm to 3.5mm balloons have a rated burst pressure of 24 atmospheres, 3.75mm to 4.0mm balloons have a rated burst pressure of 22 atmospheres and 4.5mm to 5.0mm balloons have a rated burst pressure of 20 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 bonded to a PTFE coated stainless steel tube. The proximal shaft allows for superior pushability and trackability with a smooth transition to a distal shaft.

Two radiopaque platinum/iridium marker bands are located within the balloon segment with the exception of 1.5mm balloon diameter which incorporate a centrally positioned single marker band. 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 marker 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.

**Indication for Use:**
The indication for use for Sapphire NC 24 Coronary Dilatation Catheter remains the same as the predicate device (Sapphire NC plus):

The Sapphire NC 24 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 device and reference device:

- Same indications for use
- Same catheter design
- Similar materials of construction
- Same hydrophilic coating
- Same silicone coating
- Same method of sterilization (EtO)

**Performance Test Summary:**
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
    - Dimensional Verification
    - Balloon Preparation, Deployment, and Retraction
    - Balloon Rated Burst Pressure
    - Balloon Fatigue
    - Balloon Compliance
    - Balloon Inflation and Deflation Time

- Catheter Bond Strength
- Tip Pull Strength
- Flexibility and Kink
- Torque Strength
- Marker Band Radiopacity
- Coating Integrity
- Particulate Evaluation
- Balloon Rated Burst Pressure (in-stent)
- Balloon Fatigue (in-stent)

- 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
    - Hemocompatibility
        - Hemolysis
        - Partial thromboplastin time
        - Platelet and leukocyte counts
        - Complement activation
        - *In vivo* thromboresistance
    - Pyrogenicity
    - Genotoxicity
        - bacterial mutagenicity test
        - *in vitro* mouse lymphoma Assay

- Packaging and sterilization validation

- Shelf Life

The test results met all acceptance criteria, which are same or similar to the predicate device and reference device. It ensures that the design and construction of Sapphire NC 24 Coronary Dilatation Catheter are suitable for its intended use.

**Conclusions**

This information supports a determination of substantial equivalence between the Sapphire NC 24 Coronary Dilatation Catheter and the predicate device/reference device listed above.