



August 15, 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: K233505

Trade/Device Name: Sapphire 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

Indications for Use

Submission Number (if known)

K233505

Device Name

Sapphire ULTRA Coronary Dilatation Catheter

Indications for Use (Describe)

The Sapphire ULTRA Coronary 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 ($\geq 70\%$ stenosis) for the purpose of improving myocardial perfusion.

The Sapphire ULTRA Coronary 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.

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.

Submitter Information:

510(k) Submitter: OrbusNeich Medical (Shenzhen) Co., Ltd.
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Contact person: Jerry Cheung
Job Title: Senior Director of Regulatory Affairs
Email: jcheung@orbusneich.com

Submission date: October 31, 2023

Subject Device Information:

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

Predicate Device:

Sapphire II Pro Coronary Dilatation Catheter
(K173680; cleared Mar.1, 2018)

Reference Device: Sapphire II Pro Coronary Dilatation Catheter
(K163114; cleared Jan.05, 2017)
Sapphire NC 24 Coronary Dilatation Catheter
(K211807; cleared Oct.14, 2021)
Sapphire NC Plus Coronary Dilatation Catheter
(K162209; cleared Oct.6, 2016)
(K192344; cleared Sep.19, 2019)

Device Description:

The Sapphire 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 1.0mm to 4.0mm. The balloon material is made of the semi-compliant material with a rated burst pressure of 14 atmospheres. 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 with a smooth transition to a distal shaft composed of an outer tube and an inner tube with a balloon laser welded to both tubes at the distal tip. Two radiopaque platinum marker bands are located within the balloon segment (there is only one centrally located marker band for Ø1.0-1.5mm configurations). 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, 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 ULTRA Coronary Dilatation Catheter remains the same as the predicate device (Sapphire II PRO):

The Sapphire ULTRA Coronary 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 ($\geq 70\%$ stenosis) for the purpose of improving myocardial perfusion.

The Sapphire ULTRA Coronary 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

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 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
 - Hub Leakage
 - Balloon Inflation and Deflation Time
 - Catheter Bond Strength
 - Tip Pull Strength
 - Flexibility and Kink
 - Torque Strength
 - Marker Band Radiopacity
 - Coating Integrity
 - Particulate Evaluation
 - Catheter Body Burst Pressure
 - Shaft Burst
- 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
 - Complement activation
 - Partial thromboplastin time
 - Platelet and leukocyte counts
 - Pyrogenicity
 - Extractables Assessment and Toxicological Risk Assessment (TRA) of Extractable Chemicals
- 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 ULTRA Coronary Dilatation Catheter are suitable for its intended use.

Conclusions

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