June 11, 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: K241025
Trade/Device Name: JADE PLUS PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 15, 2024
Received: April 15, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2024.06.11 11:27:39 -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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241025

Device Name
Jade PLUS PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The JADE PLUS PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilation of balloon expandable and self-expanding stents in the peripheral vasculature.

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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K241025

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:	April 15, 2024
Device:	Device Name: JADE PLUS PTA Balloon Dilatation Catheter Regulation Name: Peripheral Transluminal Angioplasty (PTA) Catheter Regulation Number: 21 CFR 870.1250 Regulatory Class: II Product Code: LIT
Primary Predicate Device:	JADE PTA Balloon Dilatation Catheter (K202231, LIT, cleared on Dec.10, 2020) This predicate has not been subject to a design-related recall.

Predicate Device:	JADE PTA Balloon Dilatation Catheter (K201794, LIT, cleared on Jul.28, 2020) This predicate has not been subject to a design-related recall.
Device Description:	The JADE PLUS Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheters are designed for peripheral indications with Over-The-Wire (OTW) structure. The over-the-wire design permits the use of standard 0.014 inch, 0.018 inch and 0.035 inch guidewires respectively.
Indications for Use:	The JADE PLUS PTA Balloon Dilatation Catheters are indicated for percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post- dilation of balloon expandable and self-expanding stents in the peripheral vasculature.
Technological Characteristics:	The subject device has the following similarities to the predicate devices: • Same indications for use • Same balloon compliance type • Same method of EO sterilization • Same hydrophilic coating • Same silicone coating • Similar catheter design • Similar materials of construction • Similar performance specifications The following technological differences exist between the subject and predicate device: • New configurations • Dimensions of components • Rated burst pressure

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 ""Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters" issued on April 14, 2023, including:

- Balloon Rated Burst Pressure
- Balloon Fatigue
- Balloon Compliance
- Balloon Rated Burst Pressure (in-stent)
- Balloon Fatigue (in-stent)
- Visual Inspection
- Marker Band Radiopacity
- Dimensional Verification
- Flexibility and Kink
- Shaft burst
- Torque Strength
- Catheter Bond Strength
- Tip Pull Strength
- Balloon Preparation, Deployment, and Retraction (Simulated Use)

- Balloon Inflation and Deflation Time
- Particulate Evaluation
- Coating Integrity

- 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 JADE PLUS PTA Balloon Dilatation Catheter design and construction are suitable for their intended use. The biocompatibility testing from the predicate device (Jade OTW series) is being leveraged for the subject device (JADE PLUS OTW LE series).

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