July 28, 2020

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

Re: K201794
Trade/Device Name: Jade PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: June 23, 2020
Received: June 30, 2020

Dear Mr. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Jade PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Jade 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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510(k) Summary

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

Submitter:	OrbusNeich Medical (Shenzhen) Co., Ltd. 1 Jinkui Road, Futian Free Trade Zone Shenzhen, 518038, China
Contact Person:	Daniel Zhang
Date Prepared:	June 19, 2020
Trade Name:	Jade PTA Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250)
Product Code:	LIT
Predicate Device:	OrbusNeich Jade (K173894; cleared February 9, 2018)
Reference Device:	Bard Ultraverse (K192318; cleared October 3, 2019) Boston Scientific Sterling (K141112; cleared July 16, 2014 & K132430; cleared October 17, 2013)
Device Description:	The JADE PTA Balloon Dilatation Catheters is now also available as an over-the-wire balloon catheter for peripheral indications. The balloon diameters range from 1.5mm to 6.0mm and balloon lengths range from 20mm to 240mm, with 90cm, 150cm and 200cm catheter lengths. The balloon material is made of a minimally compliant material with a rated burst pressure of 18 atmospheres for 5.0-6.0mm and 20atm for 1.5-4.0mm. Hydrophilic lubricious coatings are applied to the distal section of the catheter. The shaft of the catheter is composed of a proximal shaft and a distal shaft. The distal shaft is composed of a distal outer tube and tri-extrusion inner tube with a balloon welded to both tubes at the distal tip to aid in tracking through vasculature. The proximal shaft is composed of a proximal outer tube and tri-extrusion inner tube that are bonded to a female luer connector, with the proximal outer tube allowing for proximal pushability with a smooth transition to the distal shaft. The inner lumen of the catheter accepts a maximum 0.014 inch (0.36mm) guidewire. The guidewire enters the catheter tip and advances coaxially out the hub guidewire lumen. Two radiopaque marker bands are positioned within the balloon shoulder, and for balloons of working length 180-240mm, two more marker bands (four marker bands in total) are positioned in the middle of the balloon. One marked section, for the 90cm catheter working length, or two marked sections, for the 150cm and 200cm catheter working lengths, are located on the proximal shaft to indicate catheter position relative to the tip of the guiding catheter or introducer sheath. The Y-type hub is bonded on the proximal end of the catheter at the entrance to the inflation lumen and the guidewire lumen. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

Intended Use:	The JADE 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.
Technological Characteristics:	The subject and predicate devices are the same based on the following technological elements: ■ the same indications for use ■ minimally-compliant balloon ■ nominal pressure of 12 atm ■ rated burst pressure of 18/20 atm ■ distal shaft ■ hydrophilic coating on the distal section of the catheter ■ silicone coating in the inner lumen ■ 0.014" guidewire compatibility ■ EO sterilization The technological differences of the subject comparing with the predicate device are as follows: ■ over-the-wire catheter shaft design (for catheter working lengths of 90, 150 and 200cm) ■ additional balloon lengths of 150, 180, and 240mm ■ over-the-wire hub design ■ specific materials selected for proximal shaft ■ dimensions of proximal shaft components and catheter

Performance Data:

The following testing was performed to support the over-the-wire shaft design of the Jade PTA balloon dilatation catheter:

- Performance Testing
  - Visual Inspection
  - Marker Band Radiopacity
  - Dimensional Verification
  - Coating Integrity
  - Particulate Evaluation
  - Balloon Preparation, Deployment, and Retraction
  - Balloon Burst.
  - Balloon Burst (in-stent)
  - Balloon Compliance
  - Balloon Fatigue
  - Balloon Fatigue (in-stent)
  - Balloon Inflation and Deflation Time
  - Flexibility and Kink
  - Torque Strength
  - Tip Pull Strength
  - Catheter Bond Strength
- Biocompatibility
  - Cytotoxicity
  - ISO Intracutaneous Irritation
  - Sensitization ISO Guinea Pig
  - Acute Systemic Toxicity
  - Material-mediated Pyrogenicity
  - Hemocompatibility
    - Hemolysis
    - Complement Activation
    - *In vivo* Thromboresistance
  - Genotoxicity
    - Bacterial Mutagenicity
    - *In Vitro* Mouse Lymphoma Assay
- Sterilization

The test results met all acceptance criteria, which are the same or similar to the predicate device, and ensure that the Jade PTA balloon dilation catheter design and construction are suitable for its intended use.

Conclusion:

This information supports a determination of substantial equivalence between the Jade PTA balloon dilatation catheter and the predicate device described above.