December 10, 2020

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

Re: K202231
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: November 5, 2020
Received: November 9, 2020

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

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)*
K202231

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 information:

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Contact person:	Daniel Zhang Phone: +86-755-83580181-8302 Fax: +86-755-83580169
Data prepared:	August 05, 2020

Device information:

Name of Device:	JADE PTA Balloon Dilatation Catheter
Common Name:	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250)
Regulatory Class:	II
Product Code:	LIT

Predicate Device:

Predicate Device:	JADE PTA Balloon Dilatation Catheter (K173894, cleared on February 9, 2018)
Reference Devices	Ultraverse® 014 and 018 PTA Balloon Dilatation Catheters (K192318, cleared on October 3, 2019) Mustang™ Balloon Dilatation Catheter (K103751, cleared on March 22, 2011)

Device Description:

The JADE Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheters are designed for peripheral indications and include both Rapid Exchange (RX) and Over-The-Wire (OTW) designs. The over-the-wire design permits the use of standard 0.018 inch and 0.035 inch guidewires respectively (hereafter referred to as 18 OTW version and 35 OTW version), and the rapid exchange design permits the use of standard 0.018 inch guidewires (hereafter referred to as 18 RX version) as shown in Table 1 below.

Table 1. JADE PTA Balloon Dilatation Catheter and Balloon Design

Description	Compatible Guidewire	Rapid Exchange/ Over-The-Wire	Balloon Diameter	Balloon Working Length	Catheter Working Length	Shaft Marker
18 RX version	0.018 inch	Rapid Exchange	1.5-7.0mm	15-240mm	150cm	Two Markers
18 OTW version	0.018 inch	Over-The-Wire	1.5-7.0mm	15-240mm	90cm	One Marker
					150/200cm	Two Markers
35 OTW version	0.035 inch	Over-The-Wire	3.0-7.0mm	20-240mm	75/135/200cm	No Marker

The JADE PTA balloon dilatation catheter is made of a minimally compliant material with a rated burst pressure of 16 atmospheres for 7.0mm diameters, 18 atmospheres for 4.5-6.0mm diameters and 20 atmospheres for 1.5-4.0mm diameter. Two radiopaque marker bands (Platinum/Iridium) 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. A hydrophilic lubricious coating is applied to the outside surface of distal section of the catheter. A Silicone coating is applied to wire lumen surface.

For the Rapid Exchange catheter (18 RX version), the proximal shaft is composed of a female luer connector bonded to a nylon tube which is internally supported by a stainless steel hypotube. The balloons can be inflated by injecting dilute contrast media solution through the trailing hub of the catheter. The proximal part of the guidewire enters the catheter tip and advances coaxially out the RX port, thereby allowing both coaxial guidance and rapid exchange of catheter with a single standard length guidewire. Two shaft markers are located on the proximal shaft to indicate catheter position relative to the guiding catheter or guiding sheath.

For the Over-The-Wire catheter (both the 18 OTW version and 35 OTW version), the catheter consists of a proximal shaft with a Y-type hub and a distal shaft with a balloon near the distal tip. The straight port of the hub is used for the guidewire entrance and the side port is used to inflate and deflate the balloon.

- For the 18 OTW version, the external lumen provides for inflation of the balloon with dilute contrast media solution, and the internal lumen provides access for the guidewire to facilitate advancement of the catheter to and through the stenosis or stent to be dilated. One shaft marker for the 90cm catheter working length, or two shaft markers for the 150cm and 200cm catheter working lengths, are located on the proximal shaft to indicate catheter position relative to the guiding catheter or guiding sheath.
- For the 35 OTW version, a dual lumen tube has been adopted for the catheter shaft, with one lumen providing for inflation of the balloon with dilute contrast media solution, and the second lumen providing access for the guidewire to facilitate advancement of the catheter to and through the stenosis or stent to be dilated. There is no shaft marker

located on the proximal shaft.

The design of the dilatation catheters does not incorporate a lumen for distal dye injections or distal pressure measurements.

Indications for 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.

Comparison of Technological Characteristics with the Predicate Device:
The subject device has the following similarities to the predicate device:

- Same indications for use
- Same balloon compliance type
- Similar balloon 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 (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
  - Intracutaneous reactivity
  - Sensitization
  - Acute systemic toxicity
  - Hemocompatibility
    - Hemolysis
    - Complement activation
    - Partial thromboplastin time
    - Platelet and leukocyte counts
    - *In vivo* thromboresistance
  - Pyrogenicity
  - Genotoxicity
    - bacterial mutagenicity test
    - *in vitro* mouse lymphoma Assay

- Packaging and sterilization validation

- Shelf Life (Accelerated aging)

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

Conclusions

This information supports a determination of substantial equivalence between the JADE PTA Balloon Dilatation Catheter and the predicate device listed above.