February 9, 2018

OrbusNeich Medical Trading, Inc.
Mr. John D. Pazienza
Senior Director, Engineering
5363 NW 35th Avenue
Fort Lauderdale, FL 33309

Re: K173894
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: December 20, 2017
Received: December 21, 2017

Dear Mr. Pazienza:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173894

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

Submitter:	OrbusNeich Medical Trading, Inc. 5363 NW 35th Avenue Fort Lauderdale, FL 33309 Phone: 954.730.0711 Fax: 954.730.7601
Contact Person:	John D. Pazienza
Date Prepared:	February 8, 2018
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:	Sterling (K141150; cleared September 25, 2014)
Reference Devices:	Sapphire NC Plus (K162209; cleared October 6, 2016) NanoCross Elite (K141118; cleared July 18, 2014)
Device Description:	The JADE Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is a rapid exchange balloon catheter for peripheral indications with a working length of 150cm. The minimally compliant balloons, available in diameters from 1.5-6.0mm and lengths from 15-120mm, can be inflated by injecting dilute contrast media solution through the trailing hub of the catheter. The balloon material is made of a minimally compliant material with a rated burst pressure of 20 atm (∅1.5-4.0mm) or 18atm (∅4.5-6.0mm). Hydrophilic lubricious coatings are applied to the distal section of the catheter. The proximal shaft of the catheter is composed of a female luer connector bonded to a nylon tube which is internally supported by a stainless steel hypotube. Two radiopaque platinum/iridium marker bands are located within the balloon shoulders. The internal lumen of the catheter accepts a maximum 0.014 inch (0.36mm) guidewire. 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 marked sections, 3mm in length located on the proximal shaft specifically designed to be highly visible, indicate catheter position relative to the guiding catheter or guiding sheath. 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:	Comparisons of the new and predicate devices show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate devices.
Performance Data:	Both *in vitro* performance tests, such as 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 kinking, torque strength, radiopacity, coating integrity, particulate evaluation, within stent balloon burst strength, and within stent balloon fatigue and also biocompatibility tests, such as cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility (hemolysis, partial thromboplastin time, platelet and leukocyte counts, complement activation, and *in vivo* thromboresistance), pyrogenicity, and genotoxicity (bacterial mutagenicity and *in vitro* mouse lymphoma) were conducted on the Jade PTA balloon dilatation catheter. The test results met all acceptance criteria, were similar to predicate devices, and ensure that the Jade PTA balloon dilatation 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.