September 16, 2026

OrbusNeich Medical (Shenzhen) Co., Ltd.
Dora Zhang
Manager of Regulatory Affairs
#1 Jinkui Rd.
Futian Free Trade Zone
Shenzhen, 518038
China

Re: K261778
Trade/Device Name: JADE SCORE PTA Scoring Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PNO
Dated: August 13, 2026
Received: August 13, 2026

Dear Dora 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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2026.09.16 11:10:08 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261778

Please provide the device trade name(s).

JADE SCORE PTA Scoring Balloon Dilatation Catheter

Please provide your Indications for Use below.

JADE SCORE PTA Scoring 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary - K261778

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: +86-755-83580181-8326 Fax: +86-755-83580169
Contact Person:	Name: Dora Zhang Job Title: Manager of Regulatory Affairs Email: dorazhang@orbusneich.com
Date Prepared:	May 20, 2026
Device:	Name of Device: JADE Score PTA Scoring Balloon Dilatation Catheter Classification Name: Catheter, Percutaneous, Cutting/Scoring Regulatory Number: 21 CFR 870.1250 Regulatory Class: II Product Code: PNO
Predicate Device:	UltraScore Focused Force PTA Balloon (K163420, PNO. Cleared June 14, 2017) This predicate has not been subject to a design-related recall.
Reference Devices:	Scoreflex PTA Scoring Balloon Catheter (K182713, PNO, cleared May 07, 2019) JADE PLUS PTA Balloon Dilatation Catheter (K241025, LIT, cleared June 11, 2024)
Device Description:	The Peripheral Transluminal Angioplasty (PTA) Catheters are designed for peripheral indications. The JADE Score PTA Scoring Balloon Dilatation Catheter contains two device versions: JADE Score PTA Scoring Balloon Dilatation Catheter (14 Rx version) and JADE Score PTA Scoring Balloon Dilatation Catheter (18 OTW version). The JADE Score 14 Rx is designed with Rapid-exchange (Rx) structure, permits the use of standard 0.014-inch guidewire, while the JADE Score 18 OTW is designed with

	Over-The-Wire (OTW) structure, permits the use of standard 0.018-inch guidewire.
Indications For Use:	JADE Score PTA Scoring 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.
Technological Characteristics:	The subject device has the following similarities to the predicate devices: • Same indications for use • Similar catheter design • Similar materials of construction • Same hydrophilic coating • 0.014" guidewire compatibility • 5F-6F guiding catheter compatibility • Same method of EO sterilization • Same Scoring Element, element direction and element shape • Same Mechanism of Action • Similar performance specifications The following technological differences exist between the subject and predicate device: • Specific materials selected • Exact dimensions of components
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: • Visual Inspection • Dimensional Verification • Flexibility and Kink • Shaft burst • Torque Strength • Catheter Bond Strength • Leakage Test

- Corrosion Resistance
- Radiopacity
- Balloon Preparation, Deployment, and Retraction (Simulated Use)
- Balloon Inflation and Deflation Time
- Coating Integrity
- Particulate Evaluation
- Balloon Rated Burst Pressure
- Balloon Fatigue
- Balloon Compliance

➢ 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 Score PTA Scoring Balloon Dilatation Catheter design and construction are suitable for their intended use.

Conclusion: This information supports a determination of substantial equivalence between the JADE Score PTA Scoring Balloon Dilatation Catheter and the predicate device described above.