September 19, 2019

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

Re: K192344
Trade/Device Name: Sapphire NC Plus Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: August 28, 2019
Received: August 29, 2019

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. 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,

For

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)*

K192344

Device Name
Sapphire NC Plus Coronary Dilatation Catheter

Indications for Use *(Describe)*

The Sapphire NC Plus Coronary Dilatation Catheter is indicated for:

- balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion
- balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction
- in-stent restenosis
- post-delivery expansion of balloon expandable coronary stents

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 - K192344

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:	August 28, 2019
Trade Name:	Sapphire NC Plus Coronary Dilatation Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Classification Name:	Catheters, transluminal coronary angioplasty, percutaneous 21 CFR 870.5100(a)
Product Code:	LOX
Device Class:	Class II (special controls)
Predicate Device:	Sapphire NC Plus (K162209; LOX; cleared October 6, 2016)
Reference Device:	NC Euphora (K141090; LOX; cleared August 14, 2014)
Device Description:	The Sapphire NC Plus coronary dilatation catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm. The proximal shaft is a polymer coated stainless steel hypotube. Lubricious coatings are applied to the distal section. The non-compliant balloons, available in diameters from 2.0-5.0mm and lengths from 8-18mm, can be inflated by injecting dilute contrast media solution through the trailing hub of the catheter. Two radiopaque platinum marker bands are located within the balloon segment. The catheter is compatible with 5F (6F for ∅4.5-5.0mm) or larger guiding catheters. The internal lumen of the catheter accepts a standard 0.014 inch PTCA guidewire. The proximal part of the guidewire enters the catheter tip and advances coaxially out the catheter proximal port, thereby allowing both coaxial guidance and rapid exchange of catheters with a single standard length guidewire. Two marked sections are located on the hypotube shaft to indicate catheter position relative to the tip of either a brachial or femoral guiding catheter. The design of this dilatation catheter does not incorporate a lumen for distal dye injections or distal pressure measurements. This Special 510(k) describes the addition of the ∅4.5-5.0mm balloon configurations to the Sapphire NC Plus PTCA catheter family.

Intended Use:	The Sapphire NC Plus Coronary Dilatation Catheter is indicated for: • balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion • balloon dilatation of a coronary artery occlusion for the treatment of acute myocardial infarction • in-stent restenosis • post-delivery expansion of balloon expandable coronary stents
Technological Characteristics:	At a high level, the subject and predicate devices are based on the same technological elements: • indications for use • rapid exchange catheter design • non-compliant balloon • nominal pressure • 0.014" guidewire compatibility • specific materials selected • catheter working length • hydrophilic coating • EO sterilization The following technological differences exist between the subject and predicate device: • balloon diameter range • exact dimensions of components and catheter • rated burst pressure
Performance Data:	Testing was performed to support the use of the Sapphire NC Plus: • Shelf-Life • Performance Testing o Visual Inspection o Dimension Inspection o Balloon Preparation, Deployment, and Retraction o Balloon Rated Burst Pressure o Balloon Fatigue o Balloon Compliance o Balloon Inflation and Deflation Time o Catheter Bond Strength o Tip Pull Strength o Particulate Evaluation o Balloon Rated Burst Pressure (within stent) o Balloon Fatigue (within stent) The Sapphire NC Plus test results met all acceptance criteria and were similar to the predicate devices.
Conclusion:	This information supports a determination of substantial equivalence between the Sapphire NC Plus coronary dilatation catheter and the predicate device described above.