DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 6, 2016

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

Re: K162209
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: September 9, 2016
Received: September 12, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Brian D. Pullin -S

for 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)*
K162209

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

Note: The subject device was tested on the bench with the OrbusNeich Blazer Cobalt-Chromium (CoCr) Alloy Stent. All stents should be deployed in accordance with the manufacturer's indications and instructions for use.

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, 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 4, 2016
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)
Predicate Device:	Sapphire NC (K103808; cleared September 7, 2011)
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 2.0-4.0mm 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 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 modification to the Sapphire NC PTCA catheters including a change to the hydrophilic coating and also a change in the brand name to Sapphire NC Plus.

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 Note: The subject device was tested on the bench with the OrbusNeich Blazer Cobalt-Chromium (CoCr) Alloy Stent. All stents should be deployed in accordance with the manufacturer's indications and instructions for use.
Technological Characteristics:	Comparisons of the new and predicate device show that the technological characteristics such as product performance, design, and intended use are substantially equivalent to the currently marketed predicate device.
Performance Data:	To support the hydrophilic coating change, both *in vitro* performance tests such as [balloon preparation, deployment, and retraction], balloon rated burst pressure, balloon fatigue, balloon compliance, catheter bond strength, tip pull strength, coating integrity, particulate evaluation, and also biocompatibility tests such as cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility (hemolysis, complement activation, prothromboplastin time, [platelet and leukocyte counts], and *in vivo* thromboresistance), pyrogenicity, and genotoxicity (bacterial mutagenicity and *in vitro* mouse lymphoma) were conducted on the Sapphire NC Plus coronary dilatation catheter. The test results met all acceptance criteria, were similar to the predicate device, and ensure that the Sapphire NC Plus coronary dilatation catheter design and construction are suitable for its intended use as recommended by the Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (FDA; September 8, 2010).
Conclusion:	This information supports a determination of substantial equivalence between the Sapphire NC Plus coronary dilatation catheter and the predicate device described above.