



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

January 05, 2017

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

Re: K163114

Trade/Device Name: Sapphire II Pro 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: November 4, 2016  
Received: November 7, 2016

Dear John 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name. A large, light blue "FDA" watermark is visible in the background behind the signature.

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K163114

Device Name

Sapphire II PRO Coronary Dilatation Catheter

Indications for Use (Describe)

The Sapphire II PRO 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

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

K163114

**510(k) Summary**

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

Submitter: OrbusNeich Medical, Inc.  
5363 NW 35<sup>th</sup> Avenue  
Fort Lauderdale, FL 33309  
Phone: 954.730.0711  
Fax: 954.730.7601

Contact Person: John D. Paziienza

Date Prepared: November 4, 2016

Trade Name: Sapphire II PRO 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 (K103657; cleared August 9, 2011)  
Sapphire NC (K103808; cleared September 1, 2011)  
Sapphire NC Plus (K162209; cleared October 6, 2016)

Device Description: The Sapphire II PRO coronary dilatation catheter is a percutaneous transluminal coronary angioplasty (PTCA) balloon catheter with a working length of 140cm. The proximal shaft is a PTFE coated stainless steel hypotube. Hydrophilic lubricious coatings are applied to the distal section. The semi-compliant balloons, available in diameters from 1.5-4.0mm and lengths from 10-30mm, 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 (there is only one centrally located marker band for the Ø1.5mm configurations). 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.

Intended Use: The Sapphire II PRO 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

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, and particulate evaluation, 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 Sapphire II PRO coronary dilatation catheter. The test results met all acceptance criteria, were similar to predicate devices, and ensure that the Sapphire II PRO 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 II PRO coronary dilatation catheter and the predicate devices described above.