DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 18, 2016

Corindus, Inc.
% Ms. Mona Advani
Senior Consultant
CardioMed Device Consultants
5523 Research Park Drive, Suite 205
Baltimore, MD 21228

Re: K152999
Trade/Device Name: CorPath 200 System
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II
Product Code: DXX
Dated: February 19, 2016
Received: February 22, 2016

Dear Ms. Advani:

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 yours,

Kenneth J. Cavanaugh -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 on last page.

510(k) Number *(if known)*
K152999

Device Name
CorPath 200 System

Indications for Use *(Describe)*
The CorPath 200 System is intended for use in the remote delivery and manipulation of guidewires and rapid exchange catheters during percutaneous vascular interventional (PVI) procedures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 the requirements of 21 CFR Part 807, Section 807.92(c).

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Date Prepared: March 16, 2016

Device Information:

Trade Name: Corindus CorPath® 200 System
Common Name: CorPath System
Product Code: DXX (Steerable catheter control system)
Regulation Number: 21 CFR 870.1290 (Steerable catheter control system)

Predicate Device(s): Corindus CorPath 200 System (K120834, K150892)
Magellan Robotic System (K111004, K141614)

Device Description

The CorPath 200 System is intended for use by physicians in the delivery and manipulation of guidewires and rapid exchange catheters during percutaneous vascular interventional (PVI) procedures. The CorPath 200 System allows the physician to deliver and manipulate guidewires and catheters through the vasculature under angiography-assisted visual guidance using computer controlled movements while in a seated position and away from the radiation source.

Indication for Use

The CorPath 200 System is intended for use in the remote delivery and manipulation of guidewires and rapid exchange catheters during percutaneous vascular interventional (PVI) procedures.

Technological Characteristics

The CorPath 200 System is composed of two functional sub-units; the Bedside Unit and the Remote Workspace. The Bedside Unit consists of the Articulated Arm, the Robotic Drive and the single-use Cassette. The Remote Workspace consists of the Interventional Cockpit (radiation shield) which houses the Control Console, as well as angiographic monitor(s). Commercially available guidewires and rapid exchange catheters are loaded into the single-use Cassette. By using the joysticks or touch screen of the Control Console, the physician can send commands to the Robotic Drive via a communication cable that advances, retracts or rotates the guidewire, and/or advances or retracts the catheters. The CorPath 200 System's software continuously monitors the communication between the Control Console and the Robotic Drive and alerts the physician if any communication error occurs.

Performance Data

The CorPath 200 System for PVI is identical in design to the predicate CorPath 200 System for PCI and thus no new performance testing was conducted. Non-clinical testing of the predicate CorPath 200 System leveraged previously conducted bench and animal performance testing, biocompatibility, sterilization, packaging, and product shelf life testing from the predicate device, and is applicable to the CorPath 200 System for PVI. These tests demonstrated that the technological characteristics such as product performance, design and intended use are substantially equivalent to the currently marketed predicate devices.

Clinical Data

The CorPath 200 System was previously evaluated for PCI in the PRECISE Clinical Study. The PRECISE Clinical Study was a prospective, single-arm, multi-center, nonrandomized study of the CorPath 200 System. The objective of the study was to evaluate the safety and effectiveness of the clinical and technical performance of the CorPath 200 System in the delivery and manipulation of coronary guidewires and stent/balloon devices for use in PCI procedures. One hundred and sixty-four (164) subjects were enrolled and evaluated in the PRECISE Clinical Study at nine (9) clinical sites. The overall rate of clinical procedural success was 97.6%. One hundred percent of subjects achieved post-procedure stenosis of less than 30% (as evaluated by a Core Laboratory) and 97.6% of subjects had an absence of Major Adverse Cardiac Events (MACE). The overall device technical success rate was 98.8%. The PRECISE Trial demonstrated a reduction of radiation exposure to the primary operator.

The **R**obotic-**A**ssisted **P**eripheral **I**ntervention for peripheral arterial **D**isease (RAPID) Study was also conducted, which was a prospective non-randomized feasibility evaluation of the CorPath 200 System for use in the remote delivery and manipulation of guidewires and rapid exchange catheters during peripheral interventions. Subjects eligible to participate in the study had symptomatic

disease with either presence of critical limb ischemia, or lifestyle-limiting claudication requiring percutaneous transluminal angioplasty (PTA). This study enrolled 20 Rutherford Class 2 to 5 subjects. There were 29 treated lesions all of which were successfully treated with the CorPath System by either balloon angioplasty (19/29; 65.5%) or balloon angioplasty with provisional stenting (10/29; 34.5%). The primary endpoints of device success (cannulation of the target vessel) and safety (absence of SAEs during the procedure) were achieved in all cases. In addition, clinical procedural success (<50% residual stenosis in all CorPath 200 System treated lesions at the completion of the interventional procedure without an unplanned switch to the manual procedure in the absence of device-related SAEs) was achieved in all subjects. A summary of the study results is presented in the table below.

Clinical Study Outcome	Result	Observations
Device Technical Success Per Subject	100% (20/20)	All target vessels successfully cannulated with the CorPath System.
Subjects Absent Device – related SAEs during the Procedure	100% (20/20)	No subjects had a device-related SAE during the procedure.
Clinical Procedural Success	100% (29/29)	Less than 50% residual stenosis in all CorPath 200 System treated lesions at the completion of the interventional procedure without an unplanned switch to the manual procedure in the absence of device-related SAEs
Device malfunctions	0% (0/20)	No device malfunctions occurred.
Angiographic complications	0% (0/29)	No angiographic complications occurred in any of the treated lesions.
Clinical events	3/20 (15%)	Puncture site hematoma in three subjects.

Conclusion

Based on similar intended use, technological characteristics, and performance characteristics, the CorPath 200 System is substantially equivalent to the predicate devices.