



Food and Drug Administration
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October 2, 2015

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

Re: K150892
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: August 30, 2015
Received: September 2, 2015

Dear Mona 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,

A handwritten signature in black ink, appearing to read "M. D. Zuckerman", is written over a large, light gray watermark of the letters "FDA".

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Section 1.0 Indication for Use Statement

Indications for Use

510(k) Number (if known): K150892

Device Name: CorPath[®] 200 System

Indications for Use:

The CorPath 200 System is intended for use in the remote delivery and manipulation of coronary guidewires and rapid exchange balloon/stent catheters during percutaneous coronary interventional (PCI) procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Section 2.0 510(k) Summary

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

Applicant: Corindus, Inc.
309 Waverly Oaks Rd.
Suite 105
Waltham, MA 02452
(P): (508) 653-3335
(C): (267) 884-3727
(F): (508) 232-6008

Contact Person: Mona Advani
Regulatory Affairs Consulting Agent for Corindus, Inc.
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, MD 21228
Email: madvani@cardiomedllc.com
(P): (650) 575-5819
(F): (617) 663-6052

Date Prepared: September 29, 2015

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)

Device Description

The CorPath 200 System is intended for use by physicians in the delivery and manipulation of coronary guidewires and rapid exchange balloon/stent catheters during percutaneous coronary intervention (“PCI”) procedures. The CorPath 200 System allows the physician to deliver and manipulate guidewires and balloon/stent catheters through the coronary 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 coronary guidewires and rapid exchange balloon/stent catheters during percutaneous coronary intervention (PCI) 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 balloon/stent 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 balloon/stent 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

Non-clinical testing of the CorPath 200 System Device consisted of performance testing, biocompatibility, sterilization, packaging, and product shelf life testing. These tests demonstrated that the technological characteristics such as product performance, design and intended use are substantially equivalent to the currently marketed predicate device. *In vitro* bench testing conducted on the system is summarized in the table below:

Test Description
PCI Device Advancement Force Test
PCI Device Advancement Force at High Speed Test
PCI Device Velocity Test
PCI Device Continuous Move Positional Accuracy Test
PCI Device Placement Accuracy Test
PCI Device Discrete Movement Positional Accuracy Test
PCI Device Torque Test
PCI Device Rotational Velocity Test
PCI Device Wear Test
Particulate Analysis Test
PCI Device Dimensional and Functional Performance Tests

GLP animal studies were conducted to support the safety and performance of the device prior to the pivotal clinical study. This study was conducted in compliance with Good Laboratory Practice (GLP) regulations (21 CFR Part 58).

Clinical Data

The CorPath 200 System was previously evaluated 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.

In addition, a clinical study evaluating the safety and performance of the CorPath 200 System via the radial access approach was conducted in 30 patients. Of the 30 treated patients, there were no reported radial artery occlusions (RAO) and only one reported radial artery spasm (RAS) (3.3%), which occurred before engaging the CorPath System. The incidence of RAS/RAO is similar to published results for manual access procedures. No patients experienced in-hospital MACE events or adverse events related to the CorPath System. CorPath-assisted Catheterization was attempted for 36 lesions. Three (3) lesions required conversion to manual, with only one being due to device (cassette component) malfunction. Of the 36 lesions treated with the CorPath System, there was a 100% clinical success rate. Treatment outcomes were favorable and the overall safety of the alternative access approach was established in this study.

Clinical Study Outcome	Results
MACE	0% (0/30)
Clinical Success	100% (36/36)
Technical Success	91.7% (33/36)
Radial Artery Spasm	3.3% (1/30)
Radial Artery Occlusion	0% (0/30)
Serious Adverse Events	3.3% (1/30)

Conclusion

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