DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 27, 2016

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

Re: K160121
Trade/Device Name: Corpath GRX System
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II
Product Code: DXX
Dated: October 21, 2016
Received: October 24, 2016

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,

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)*
K160121

Device Name
CorPath GRX System

Indications for Use *(Describe)*
The CorPath GRX is intended for use in the remote delivery and manipulation of guidewires and rapid exchange balloon/stent catheters, and remote manipulation of guide catheters during percutaneous coronary intervention (PCI) 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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).

1. SUBMITTER/510(K) HOLDER

Company Name and Address: Corindus Inc.
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Date Prepared: October 21, 2016

2. DEVICE NAME

Proprietary Name:	CorPath GRX
Common/Usual Name:	CorPath GRX System
Product Code:	DXX (Steerable catheter control system)
Classification Name:	Steerable Catheter Control System

3. PREDICATE DEVICE

- CorPath 200 System manufactured by Corindus, Inc., K120834 and K150892.

4. DEVICE DESCRIPTION

The CorPath GRX System is intended to allow physicians to deliver and manipulate commercially available coronary guidewires, rapid exchange balloon/stent catheters, and guide catheters during percutaneous coronary intervention (PCI) procedures. During the use

of the CorPath GRX System, the physician maneuvers interventional devices using intuitive controls under independent angiographic fluoroscopy visual guidance using computer controlled movements while in a seated position away from the radiation source.

5. INDICATION FOR USE

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

6. TECHNOLOGICAL CHARACTERISTICS

The CorPath GRX System is intended to allow physicians to deliver and manipulate commercially available coronary guidewires, balloon/stent catheters, and guide catheters during percutaneous coronary intervention (PCI) procedures. During the use of the CorPath GRX System, the physician maneuvers interventional devices using intuitive controls under independent angiographic fluoroscopy.

The CorPath GRX System is composed of the following two functional sub-units:

1. Bedside Unit: Which consists of the Articulated Arm, Robotic Drive and Single–use Cassette, and the
2. Remote Workspace: Which consists of the Interventional Cockpit (radiation shielded) which houses the Control Console, angiographic monitor(s), hemodynamic monitors and X-ray foot pedal.

Commercially available guidewires, rapid exchange balloon/stent catheters, and guide catheters are loaded into the Single Use Cassette. By using the joysticks or the Control Console touch screens the physician can control the Robotic Drive to advance, retract, and rotate the guide wire, advance and retract the balloon/stent catheter, and advance, retract and rotate the guide catheter. The Robotic Drive and Control Console communicate via a single communication cable.

7. Substantial Equivalence

The product subject of this premarket notification is substantially equivalent in design and functionality to the CorPath 200 System (K120834, K150892).

The table below compares the technical characteristics of the CorPath GRX System to the predicate CorPath 200 System.

Characteristics	CorPath GRX System (Subject Device, previously described as the CorPath 300 System)	CorPath 200 System K150892 and K120834 (Predicate Device)
Manufacturer	Corindus, Inc.	Corindus, Inc.
Indication for use	The CorPath GRX System is intended for use in the remote delivery and manipulation of coronary guidewires and rapid exchange balloon/stent catheters, and remote manipulation of guide catheters during percutaneous coronary intervention (PCI) procedures.	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.
Intended use	Percutaneous coronary intervention (PCI) procedures	Percutaneous coronary intervention (PCI) procedures
Device Design	The CorPath GRX System is composed of: Control Console Remote Workspace Articulated Arm Robotic Drive Cassette (single-use)	The CorPath 200 System is composed of: Control Console Remote Workspace Articulated Arm Robotic Drive Cassette (single-use)
Operational principles	The physician, seated at the Remote Workspace manipulates coronary guidewires, balloon/stent catheters and guide catheters using joysticks or touch-screen controls on the Control Console	The physician, seated at the Remote Workspace, manipulates coronary guidewires and/or balloon/stent catheters using joysticks or touch-screen controls on the Control Console.
Visualization during Procedure	Fluoroscopy	Fluoroscopy
Compatible with Commercially available PCI Devices	Yes, compatible with commercially available: • Guide catheters • Guidewires • Rapid Exchange balloon/stent catheters	Yes, compatible with commercially available: • Guidewires • Rapid Exchange balloon/stent catheters
Linear movement of PCI devices	Yes, allows for linear movement of: • Guidewires • Rapid exchange balloon/stent catheters • Guide Catheters	Yes, allows for linear movement of: • Guidewires • Rapid Exchange balloon/stent catheters
Rotational movement of PCI devices	Yes, allows for rotational movement of: • Guidewires • Guide Catheters	Yes, allows for rotational movement of: • Guidewires
Materials (single-use Cassette)	The single-use sterile Cassette is assembled from a variety of custom plastic parts and machined stainless steel components, as well as off-the-shelf miniature magnets, roller bearings and springs.	The single-use sterile Cassette is assembled from a variety of custom plastic parts and machined stainless steel components, as well as off-the-shelf miniature magnets, roller bearings and springs.

Bench Testing

Bench testing and in-vivo animal studies were performed to determine substantial equivalence. Specifically, the following bench tests were performed.

- Performance testing of the CorPath GRX System
- Functional testing of the CorPath GRX System
- Guide Catheter Particulate Analysis
- Simulated Procedure Testing
- Biocompatibility Testing of the Single-Use Cassette
- Software verification and validation testing
- EMC Testing of the CorPath GRX System

Pre-Clinical Study

To further verify the safety of the CorPath GRX System, an in-vivo porcine study was conducted. Eight (8) pigs underwent PCI (balloon angioplasty and stent deployment) of the mid left anterior descending artery (LAD) performed using the CorPath GRX System and the results were compared to a four (4) pig control group which was treated manually.

8. Conclusion

Based on the testing conducted, it is concluded that the CorPath GRX System is substantially equivalent to the predicate CorPath 200 system (K150892 cleared October 2, 2015 and K120834 cleared July 19, 2012).