February 15, 2018

Corindus, Inc.
Robert Lavado
Manager, Regulatory Affairs
309 Waverley Oaks Road
Waltham, Massachusetts 02452

Re: K173288
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: January 12, 2018
Received: January 16, 2018

Dear Robert Lavado:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173288

Device Name
CorPath GRX System

Indications for Use *(Describe)*

The CorPath GRX System is intended for use in the remote delivery and manipulation of guidewires and rapid exchange catheters, and remote manipulation of guide catheters during percutaneous coronary and vascular 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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6.0 510(K) SUMMARY

Submitter's Name and Address:	Corindus, Inc. 309 Waverley Oaks Road Suite 105 Waltham, MA 02452
Establishment Registration Number:	3007822508
Date of Summary:	February 15, 2018
Contact Person: **Telephone Number:** **Fax Number:**	Robert Lavado, Manager, Regulatory Affairs (508) 653-3335 x211 (508) 653-3355
Name of the Device:	CorPath GRX System
Common Name:	CorPath GRX System
Regulatory Status and Regulation Number:	Class II 21 CFR 870.1290
Classification Name:	System, Catheter Control, Steerable
Device Classification:	Product Code: DXX: Steerable Catheter Control System.
Indications for Use:	The CorPath GRX System is intended for use in the remote delivery and manipulation of guidewires and rapid exchange catheters, and remote manipulation of guide catheters during percutaneous coronary and vascular procedures.
Identification of the Legally Marketed Device (Predicate Device):	<u>Primary Predicate:</u> CorPath 200 System Device Class**:** II Product Code: DXX Regulation Number: 21 CFR 870.1290 510(k) number: K152999 <u>Reference Predicate:</u> CorPath GRX System

Device Class**:**	II
Product Code:	DXX
Regulation Number:	21 CFR 870.1290
510(k) Number:	K160121

Device Description:

The CorPath GRX System is intended to allow physicians to deliver and manipulate commercially available guidewires, rapid exchange catheters and guide catheters during percutaneous coronary and vascular intervention 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.

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

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

Commercially available guidewires, rapid exchange catheters, and guide catheters are loaded into the Single-use Cassette. By using the joysticks or the Control Console touch screen, the physician can control the Robotic Drive to advance, retract, and rotate the guidewire, advance and retract the rapid exchange catheter, and advance, retrace, and rotate the guide catheter. The Robotic Drive and Control Console communicate via a single communication cable.

Substantial Equivalence:

The product subject of this premarket notification is substantially equivalent in design and functionality to the CorPath GRX System (**K160121**, cleared October 27, 2016); and the CorPath 200 System (**K152999**, cleared March 18, 2016).

The modified CorPath GRX System and the predicate CorPath GRX System have the same technological characteristics. There have been no changes to the modified CorPath GRX System with respect to design, materials, packaging, sterilization, or method of action.

The CorPath GRX System uses the same method of action for driving guidewires and catheters as the predicate CorPath 200 System. The predicate CorPath 200 System was evaluated in a clinical setting and found to be safe for use in the periphery (reference **K152999**).

Verification/validation testing of the CorPath GRX System has been conducted to demonstrate the modified CorPath GRX Systems is substantially equivalent to the predicate devices. Tests conducted were identified on the basis of risk analysis activities performed to evaluate the impact of the modification on the device/components.

Specifically, the following non-clinical laboratory tests were performed to determine substantial equivalence:

- Device Compatibility Testing
- Simulated Use Testing

All testing has demonstrated that the device is substantially equivalent to the predicate devices.

Safety and Performance:

The determination of substantial equivalence for this device was based on a detailed device description and non-clinical laboratory testing. The testing demonstrated that the device is safe for its intended use and can be considered substantially equivalent to the predicate devices. Previously conducted clinical evaluation of the predicate device (reference **K152999**) demonstrates that the device is safe for use in a clinical setting.

Conclusion:

Based on the bench testing conducted, it is concluded that the CorPath GRX System is substantially equivalent to the predicate devices: the CorPath 200 System (**K152999**, cleared March 18, 2016) and the CorPath GRX System (**K160121**, cleared October 27, 2016).