December 11, 2020

Corindus, Inc.
Dana Hartlein
Regulatory Affairs Specialist
309 Waverley Oaks Road, Suite 105
Waltham, Massachusetts 02452

Re: K202275
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: August 7, 2020
Received: August 11, 2020

Dear Dana Hartlein:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202275

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.

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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:	August 7, 2020
Contact Person: **Telephone Number:** **Fax Number:**	Dana Hartlein, Regulatory Affairs Specialist W: (508) 653-3335 x215 (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):	CorPath GRX System Device Class**:** II Product Code: DXX Regulation Number: 21 CFR 870.1290 510(k) Number: K173806 (Primary Predicate) K173288 (Reference Predicate)
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 procedures. During the use of the CorPath GRX System, the physician controls the movement and maneuvering of the 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, retract, and rotate the guide catheter. The Robotic Drive and Control Console communicate via a single communication cable.

In addition, the CorPath GRX Software contains the following functionality for automated movements (also referred to as the technIQ™ automated movements), of the interventional devices:

- Rotate on Retract – When selected, rotates the guidewire a set amount upon retraction of the guidewire joystick to facilitate redirection of the guidewire while it is being navigated to the target location (previously cleared under CorPath GRX System, **K173806**).
- Wiggle – When selected, this movement enables a small clockwise and counterclockwise rotation of the guidewire while advancing to assist in navigation.
- Spin – When selected, this movement will enable a large clockwise and counterclockwise rotation of the guidewire while advancing to assist in lesion crossing.
- Constant Speed – When selected, the guidewire or device joysticks will advance and retract at a constant speed of either 2mm/second or 5mm/second depending on the speed selected by the operator.

- Dotter – When selected, this movement will enable a linear back and forth motion of the device when advancing to assist in lesion crossing and delivery of therapy.

Substantial Equivalence:

The product subject of this premarket notification is substantially equivalent in design and functionality to the CorPath GRX System (**K173806**, Primary Predicate cleared March 1, 2018; and **K173288**, Reference Predicate cleared February 15, 2018).

The proposed CorPath GRX System and the predicate CorPath GRX System have the same technological characteristics. The modified CorPath GRX System consists of software changes to include 4 additional automated features; spin, wiggle, dotter, and constant speed. There have been no additional changes to the modified CorPath GRX System with respect to materials, packaging, sterilization, or indication.

Verification/validation testing of the CorPath GRX System has been conducted to demonstrate the modified CorPath GRX Systems is substantially equivalent to the predicate device. 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:

- Functional Testing
- Simulated Use Testing
- Particulate Testing
- Software Verification and Validation testing
- Cybersecurity Penetration Testing

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

Clinical data from the post-market PRECISION GRX Study was used to help demonstrate substantial equivalence.

The technIQ automated moves for the CorPath GRX System do not change the safety profile of the device as there is no change to delivery forces and the operator maintains complete control of all movements of the devices.

Safety and Performance:	The determination of substantial equivalence for this device was based on a detailed device description, non-clinical performance testing, and supplemental clinical data. The performance testing and clinical data demonstrate the device is considered substantially equivalent to the predicate device.
Conclusion:	Based on the bench testing conducted, it is concluded that the CorPath GRX System is substantially equivalent to the Primary Predicate CorPath GRX System (**K173806**) and the CorPath GRX System Reference Predicate (**K173288)**.