K120834
P 1 of 5

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.
11 Erie Drive
Natick, MA 01760, USA
Michail M. Pankratov, MD, PhD
Vice President, Clinical and Regulatory Affairs
Email: Michail.Pankratov@Corindus.com
Telephone: (508) 653-3335 x 206
Fax: (508) 589-4050
Cell: (617) 480-4543

JUL 19 2012

Contact Person: Mona Advani
Regulatory Affairs Consulting Agent for Corindus, Inc.
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 360
Baltimore, MD 21228
Email: madvani@cardiomedllc.com
(P): (650) 575-5819
(F): (617) 663-6052

Date Prepared: March 16, 2012

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):

1. Niobe® MNS w/Navigant ™ Navigation Workstation (K060967)
2. Sensei® Robotic Catheter System (K091808)

Summary of Comparison of the CorPath 200 System to Predicate Devices

Device Name / Comparison Criteria	CorPath 200 System	Sensei Robotic Catheter System	Niobe MNS w/Navigant Navigation Workstation (NWS05)
Manufacturer	Corindus, Inc.	Hansen Medical, Inc.	Stereotaxis, Inc.
510(k) Number	TBD	K091808	K060967
Product Code	DXX	DXX	NDQ
Regulation Number	21 CFR 870.1290	21 CFR 870.1290	21 CFR 870.1290
Device Class	II	II	II
Intended Use	Remote delivery and manipulation of coronary guidewires and balloon/stent catheters.	Remote manipulation and positioning of robotically steerable catheters.	Remote navigation of magnetically-adapted coronary guidewires and catheters.
Indications for Use	Percutaneous Coronary Intervention (PCI)	Cardiac Mapping	Navigation through coronary vasculature Cardiac Mapping
Device Design	The CorPath 200 System is composed of: a Remote Workspace with an operator interface and a Bedside Unit with a robotic drive.	The Sensei Robotic Catheter System is composed of a Remote Workstation with an operator interface, a robotic arm and a control catheter.	The Stereotaxis Niobe MNS with Navigant System is composed of a Remote Workstation with an operator interface and a magnetic navigation system.
Operational Principles	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.	The physician, seated at the Remote Workstation, manipulates catheters using joysticks or track ball controls.	The physician, seated at the Remote Workstation, manipulates magnetic coronary devices through use of joysticks and/or touch screen technology.

Device Name / Comparison Criteria	CorPath 200 System	Sensei Robotic Catheter System	Niobe MNS w/Navigant Navigation Workstation (NWS05)
Use of Fluoroscopy	Yes	Yes	Yes

Device Description

The CorPath 200 System is intended for use by physicians in the delivery and manipulation of coronary guidewires and 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 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.

A comparison of the device design shows that there is substantial equivalence between the CorPath 200 System and the predicate devices. All products are designed for the remote navigation of devices through the heart vasculature. All robotic systems are composed of a bedside unit and a remote workstation. In all robotic system the navigation of devices is accomplished by use of joysticks or track balls and touch-screen controls by the physician seated in a remote seated positioned.

The CorPath 200 System uses an electromechanical interface to manipulate commercially available PCI devices. In contrast, in the case of the Niobe MNS system, navigation is achieved through the use of magnetic fields. Also in contrast to the CorPath 200 System, in the case of the Sensei Robotic system, navigation is achieved through the use of a mechanical interface.

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.

Biocompatibility testing conducted on the system is summarized in the table below:

Test Description
Cytotoxicity
Sensitization (Guinea Pig Maximization)
Intracutaneous Reactivity (Irritation)
Systemic / Acute Toxicity
Hemocompatibility (Hemolysis – direct contact method)
Hemolysis - Partial Thromboplastin Time (PTT)
Hemolysis-Platelet & Leukocyte (P&L)
Material-Mediated Pyrogenicity

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

Additionally, GLP animal studies were conducted to support the safety and performance of the device prior to the pivotal clinical study. The purpose of the GLP Studies was to evaluate the performance of the CorPath 200 System for Delivery and Deployment of Standard PTCA Devices in a porcine model acutely and at 30 days. The study was titled "Robotically-Assisted PCI: Evaluation of CorPath 200 System for

Delivery and Deployment of Standard PTCA Devices in Acute and 30-day Chronic Swine" to support the design and development of the CorPath 200 System. This study was conducted in compliance with Good Laboratory Practice (GLP) regulations (21 CFR Part 58).

Clinical Data

The CorPath 200 System was 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%. Although there were some limitations with the collection of operator radiation exposure data, the PRECISE trial results show a reduction in radiation exposure to the primary operator.

Conclusion

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 19 2012

Corindus, Inc.
c/o Mona Advani
Regulatory Affairs Consulting Agent
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 360
Baltimore, MD 21228

Re: K120834
Trade/Device Name: Corindus CorPath® 200 System
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable catheter control system
Regulatory Class: Class II
Product Code: DXX
Dated: May 25, 2012
Received: May 29, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

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 balloon/stent catheters during percutaneous coronary intervention (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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120834