DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 19, 2014

Roxwood Medical, Inc.
Mehrdad Farhangnia
President & CEO
400 Seaport Ct, Suite #103
Redwood City, California 94063

Re: K140910
Trade/Device Name: CenterCross Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 7, 2014
Received: November 10, 2014

Dear Mr. Farhangnia,

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,

Melissa A. Torres -S

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 STATEMENT

510(k) Number (if known): K140910

Device Name: CenterCross Catheter

Indications For Use:

The CenterCross Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

510(k) Notification K 140910

GENERAL INFORMATION

Applicant:
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Redwood City, CA 94063
U.S.A.
Phone: 408.373.4751
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Contact Person:
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U.S.A.
Phone: 408.373.4751
FAX: 650.779.4554

Date Prepared: April 28, 2014

DEVICE INFORMATION

The CenterCross Catheter is a percutaneous catheter for use in the coronary and peripheral vasculature.

Trade Name:
CenterCross Catheter

Generic/Common Name:
Percutaneous Catheter

Classification:
21 CFR§870.1250, Class II

Product Code:
DQY

510(k) SUMMARY (CONT.)

PREDICATE DEVICE(S)

- Roxwood Medical, MultiCross Support Catheter (K121763)
- Radius Medical, Prodigy Support Catheter (K130714)

INDICATIONS FOR USE

The CenterCross Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices.

PRODUCT DESCRIPTION

The CenterCross Catheter is a sterile, single-use, single lumen over-the-wire support catheter to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature to facilitate exchange of guidewires and other interventional devices.

The CenterCross Catheter consists of an inner shaft, outer sheath, and a proximal handle that allows for manual device manipulation and a means for flushing the catheter lumen. A key element of the device is a temporarily expandable and retractable nitinol structure, which when deployed by the physician expands to the width of the artery to aid interventionalists in establishing greater support near the treatment site.

Subsequent to conventional guidewire placement, atherectomy devices, PTCA catheters, and/or stents may be used to provide therapeutic benefit. The CenterCross Catheter in and of itself does not provide therapeutic benefit beyond simple facilitation of guidewire support. The CenterCross Catheter is similar in its design and it achieves its intended use by means of the same mechanisms as the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the CenterCross Catheter are similar to the predicate devices. Performance data is provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The CenterCross Catheter is substantially equivalent to the Roxwood Medical MultiCross Support Catheter and the Radius Medical Prodigy Support Catheter. The subject device and the predicate devices are percutaneous catheters. The proposed indications for use for the CenterCross Catheter are substantially equivalent to the indications for use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the CenterCross Catheter is substantially equivalent to the predicate devices.

510(k) SUMMARY (CONT.)

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Extensive bench testing was conducted on the CenterCross Catheter to evaluate the performance of the device and to support a determination of substantial equivalence to the predicate devices. Non-clinical testing assessed the following aspects of the device:

Nonclinical Testing Summary:

- Tensile Strength
- Torque Strength
- Simulated Use
  - Catheter Compatibility
  - Guidewire Compatibility
  - Delivery, Deployment and Retraction
  - Durability
  - Contrast Injection
- Flexibility & Kink Resistance
- Leak
- Particulate
- Expansion Force
- *In vivo* animal validation study
- Biocompatibility
- Sterilization Adoption into a validated sterilization process
- Packaging and shelf-life

All testing was performed in accordance with recognized standards. The collective results of the non-clinical testing demonstrate that the CenterCross Catheter meets the established specifications necessary for consistent performance for its intended use and is substantially equivalent to the predicate devices.

CONCLUSION

The CenterCross Catheter is a percutaneous vascular catheter and shares its design and mechanism of action with the identified predicate devices. The results of the performance testing confirm that the CenterCross Catheter functions to its specifications and intended use and exhibit the appropriate characteristics of a percutaneous vascular support catheter. The CenterCross Catheter is substantially equivalent to the predicate devices in terms of technological characteristics, intended use and performance. No new issues of safety or effectiveness are raised by the CenterCross Catheter.

SUMMARY

The CenterCross Catheter is substantially equivalent to the predicate devices.