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

January 26, 2016

Roxwood Medical, Inc.
Grace Li
Director, QA
400 Seaport Ct,
Suite #103
Redwood City, California 94063

Re: K152456
Trade/Device Name: CenterCross Ultra Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 23, 2015
Received: December 28, 2015

Dear Grace Li:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152456

Device Name
CenterCross Ultra Catheter

Indications for Use *(Describe)*

The CenterCross Ultra 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.

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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SECTION 5. 510(k) SUMMARY

510(k) Notification K152456

GENERAL INFORMATION

Applicant:

Roxwood Medical, Inc.
400 Seaport Court, Suite #103
Redwood City, CA 94063
Phone: (650) 779-4555
Fax: (650) 779-4554

Contact Person:

Grace Li
Roxwood Medical, Inc.
400 Seaport Court, Suite #103
Redwood City, CA 94063
Phone: (650) 779-4559
Fax: (650) 779-4554

Date Prepared: August 26, 2015

DEVICE INFORMATION

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

Trade Name:

CenterCross Ultra Catheter

Generic/Common Name:

Percutaneous Catheter

Classification:

21 CFR§870.1250, Class II

Product Code:

DQY

PREDICATE DEVICE(S)

CenterCross Catheter (Roxwood Medical, Inc., K140910)

INDICATIONS FOR USE

The CenterCross Ultra 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 Ultra 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 Ultra Catheter consists of an outer shaft and a removable handle/inner shaft assembly that allows for manual device manipulation. A key element of the device is an expandable and retractable nitinol structure, which, when deployed by the physician, expands to the artery wall 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 Ultra Catheter in and of itself does not provide therapeutic benefit beyond simple facilitation of guidewire and device support. The CenterCross Ultra Catheter is similar in its design and achieves its intended use by means of the same mechanisms as the predicate device.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the CenterCross Ultra Catheter are similar to the predicate device. The technological characteristic distinctive to the CenterCross Ultra is that the handle/inner shaft assembly is removable, allowing introduction of larger interventional devices. Performance data is provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The CenterCross Ultra Catheter is substantially equivalent to the CenterCross Catheter (Roxwood Medical, Inc., K140910). The subject device and the predicate devices are percutaneous catheters. The proposed indications for use for the CenterCross Ultra Catheter are substantially equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any

new issues of safety or effectiveness. Thus, the CenterCross Ultra Catheter is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

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

Nonclinical Testing Summary:

- Dimensional Inspection
- Hydrophilic Coating
- Simulated Use
- Contrast Flush Injection
- Leak
- Torque Strength
- Tip Flexibility & Kink Resistance
- Pressurized Flow Rate
- Tensile Strength
- Particulate
- Shelf-life

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

CONCLUSION

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

SUMMARY

The CenterCross Ultra Catheter is substantially equivalent to the predicate device.