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

March 4, 2016

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

Re: K152957
Trade/Device Name: MultiCross Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 3, 2016
Received: February 4, 2016

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)*
K152957

Device Name
MultiCross Catheter

Indications for Use *(Describe)*
The MultiCross Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary or peripheral vasculature and for guidewire exchange.

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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SECTION 5. 510(k) SUMMARY

510(k) Notification K152957

GENERAL INFORMATION

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

Contact Person:
Grace Li
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400 Seaport Court, Suite #103
Redwood City, CA 94063
Phone: (650) 779-4559
Fax: (650) 779-4554

Date Prepared: October 6, 2015

DEVICE INFORMATION

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

Trade Name:
MultiCross Catheter

Generic/Common Name:
Percutaneous Catheter

Classification:
21 CFR§870.1250, Class II

Product Code:
DQY

PREDICATE DEVICE(S)

MultiCross Catheter (K121763)
This predicate has not been subject to a design-related recall.

INDICATIONS FOR USE

The MultiCross Support Catheter is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary or peripheral vasculature and for guidewire exchange.

The Indications for Use statement is identical to the predicate device.

PRODUCT DESCRIPTION

The MultiCross Catheter consists of an inner shaft, outer shaft, 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 an expandable and retractable nitinol scaffold, which, when deployed by the physician, expands to the artery wall to aid the user in establishing greater support near the treatment site.

Subsequent to conventional guidewire placement, interventional tools such as angioplasty, stent, and atherectomy devices, may be used to provide therapeutic benefit. The MultiCross Catheter in and of itself does not provide therapeutic benefit beyond simple facilitation of guidewire support. The MultiCross Catheter is similar in its design and it achieves its intended use by means of the same mechanisms as the predicate device.

TECHNOLOGICAL CHARACTERISTICS

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

SUBSTANTIAL EQUIVALENCE

The MultiCross Catheter is substantially equivalent to its predicate device. The minor design modifications outlined in this Special 510(k) do not 1) affect the indications for use or 2) alter the fundamental scientific technology of the predicate device. The modified device shares the same intended use, the same technological characteristics and the same principles of operation as the predicate device. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the MultiCross Catheter is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Extensive bench testing was conducted on the MultiCross 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:

- Catheter Inspection
- Open/Close Force
- Simulated Use
- Tensile Strength
- Particulate
- EO Residuals

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

CONCLUSION

The MultiCross 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 MultiCross Catheter functions to its specifications and intended use and exhibit the appropriate characteristics of a percutaneous vascular catheter. The MultiCross 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 MultiCross Catheter.

SUMMARY

The MultiCross Catheter is substantially equivalent to the predicate device.