



Food and Drug Administration
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June 17, 2016

Roxwood Medical, Inc
Cathy Mantor
Director, Quality & Regulatory
400 Seaport Ct, Suite 103
Redwood City, California 94063

Re: K160681
Trade/Device Name: CenterCross Ultra Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 19, 2016
Received: May 20, 2016

Dear Cathy Mantor:

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

Indications for Use

510(k) Number (*if known*)
K160681

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.

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 K160681

GENERAL INFORMATION

Applicant:

Roxwood Medical, Inc.
400 Seaport Court, Suite #103
Redwood City, CA 94063, USA
Establishment Registration: #3010034168

Contact Person:

Cathy Mantor
Director, Quality & Regulatory
Phone: (510) 499-0253
Fax: (650) 779-4554

Date Prepared: March 9, 2016

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 Ultra Catheter (K152456)

The predicate has not been subject to a design-related recall.

REFERENCE DEVICE(S)

Turnpike Catheter (Vascular Solutions, Inc., K142065)

MicroCross Catheter (Roxwood Medical, Inc., K151082)

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.

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

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 differences arise from minor modifications to the handle, prime port, scaffold diameter, and shaft materials. Performance data is provided to support the determination of substantial equivalence.

SUBSTANTIAL EQUIVALENCE

The CenterCross Ultra Catheter is substantially equivalent to its predicate device. The minor design and labeling modifications outlined in this Special 510(k) do not 1) affect the intended use nor 2) alter the fundamental scientific technology of the predicate device. The modified device shares the same intended use, indications for use, and 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 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:

- Dimensional Inspection
- Expansion Force
- Simulated Use

- Hydrophilic Coating
- Leak
- Contrast Flush Injection
- Tip Flexibility & Kink Resistance
- Torque Strength
- Tensile Strength
- Particulate
- Radiopacity
- Corrosion
- LAL
- EO Residuals
- Packaging and Shelf-Life
- Biocompatibility

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.