



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 7, 2015

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

Re: K151082  
Trade/Device Name: MicroCross Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: May 18, 2015  
Received: May 19, 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

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

MicroCross Catheter

Indications for Use (Describe)

The MicroCross Catheter is intended for use as a conduit for the exchange/support of guidewires in the peripheral and coronary vasculatures. The MicroCross Catheter is also intended to infuse and deliver saline and contrast agents.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**510(k) Summary: K151082**

**GENERAL INFORMATION**

**Applicant:**

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

**Contact Person:**

Grace Li  
Roxwood Medical, Inc.  
400 Seaport Ct., Suite #103  
Redwood City, CA 94063  
Phone: (650) 779-4555  
FAX: (650) 779-4554

**Date Prepared:** April 21, 2015

**DEVICE INFORMATION**

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

**Trade Name:**

MicroCross Catheter

**Generic/Common Name:**

Percutaneous Catheter

**Classification:**

21 CFR§870.1250, Class II

**Product Code:**

DQY

**PREDICATE DEVICE(S)**

MicroCross Catheter (K143744)

### **INDICATIONS FOR USE**

The MicroCross Catheter is intended for use as a conduit for the exchange/support of guidewires in the peripheral and coronary vasculatures. The MicroCross Catheter is also intended to infuse and deliver saline and contrast agents.

### **PRODUCT DESCRIPTION**

The MicroCross Catheter is a sterile, single-use, single lumen over-the-wire catheter to be used for the exchange and support of guidewires in the peripheral and coronary vasculatures. The MicroCross Catheter also infuses and delivers saline and contrast agents.

The MicroCross Catheter consists of a catheter shaft and a proximal hub that provides strain relief. The MicroCross Catheter is offered with a working length of 155cm and is compatible with 0.018” diameter guidewires, 5F guide catheters, and 4F introducer sheaths.

Subsequent to conventional guidewire placement, interventional tools such as angioplasty, stent, and atherectomy devices, may be used to provide therapeutic benefit. The MicroCross Catheter in and of itself does not provide therapeutic benefit beyond simple facilitation of guidewire support. The MicroCross 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 MicroCross Catheter are similar to the predicate device. Performance data is provided to support the determination of substantial equivalence.

### **SUBSTANTIAL EQUIVALENCE**

The MicroCross 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 MicroCross Catheter is substantially equivalent to the predicate device.

## **TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION**

Extensive bench testing was conducted on the MicroCross 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
- Kink Resistance & Flexibility
- Pressurized Flow Rate
- Tensile Strength
- Particulate
- LAL

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

## **CONCLUSION**

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

## **SUMMARY**

The MicroCross Catheter is substantially equivalent to the predicate device.