DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 7, 2017

RenovoRx, Inc.
% Ronald S. Warren
Sr. Director, Regulatory Affairs
Experien Group, LLC
755 N. Mathilda Avenue, Suite 100
Sunnyvale, CA 94085

Re: K160067
Trade/Device Name: RenovoCath™ RC120 Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: February 23, 2017
Received: February 24, 2017

Dear Ronald S. Warren:

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,

Fernando Aguel -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)*
K160067

Device Name
RenovoCath™ RC120 Catheter

Indications for Use *(Describe)*
The RenovoCath™ RC120 Catheter is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. The RenovoCath™ RC120 is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The RenovoCath™ RC120 is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath™ RC120 is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 4mm to 11mm in diameter.

The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the respective agent manufacturer.

The RenovoCath™ RC120 Catheter is not intended for use in coronary and intracranial arteries.

The RenovoCath™ RC120 Catheter is not intended for embolic protection or as an aspiration catheter.

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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510(k) SUMMARY

510(k) Notification K160067

GENERAL INFORMATION

Applicant:
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Los Altos, CA 94022
USA
Phone: 1-650-284-4433

Contact Person:
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San Jose, CA 95110
U.S.A.
Phone: 1-408-505-3926
FAX: 1-408-400-0865
Date Prepared: March 7, 2017

DEVICE INFORMATION

Trade/Proprietary Name:
RenovoCath™ RC120 Catheter
Generic/Common Name:
Catheter, Intravascular Occluding, Temporary
Classification:
21 CFR§870.4450, Vascular clamp
Product Code:
MJN, Catheter, Intravascular Occluding, Temporary

PREDICATE DEVICE(S)

Boston Scientific Equalizer™ Occlusion Balloon Catheter (K140273)

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

INDICATIONS FOR USE

The RenovoCath™ RC120 Catheter is intended for the isolation of blood flow and delivery of fluids, including diagnostic and/or therapeutic agents, to selected sites in the peripheral vascular system. The RenovoCath™ RC120 is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The RenovoCath™ RC120 is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath™ RC120 is intended for use in arteries

from 3mm in diameter for vessel entry and to occlude vessels ranging between 4mm to 11mm in diameter.

The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the respective agent manufacturer.

The RenovoCath™ RC120 Catheter is not intended for use in coronary and intracranial arteries.

The RenovoCath™ RC120 Catheter is not intended for embolic protection or as an aspiration catheter.

PRODUCT DESCRIPTION

The RenovoCath™ RC120 Catheter ("RenovoCath") is a multi-lumen, dual-balloon catheter. The distance between the proximal and distal balloons is adjustable. The RenovoCath is provided with two off-the-shelf 3cc syringes that facilitate precise inflation of the balloons under fluoroscopic guidance.

SUMMARY OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS COMPARISON

The indications for use for the RenovoCath are substantially equivalent to the indications for use for the predicate device. Both devices have the same intended use and similar technological characteristics. In addition, the bench testing on the predicate device confirms that functionally the Equalizer Catheter and RenovoCath have similar design features to facilitate the delivery of fluids to the peripheral vasculature. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the RenovoCath is substantially equivalent to the predicate device.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

There are no design changes of the RenovoCath requiring new testing. Reference is made to previous bench testing conducted on the RenovoCath which supported the original 510(k) clearance of K141175. That testing included biocompatibility, sterilization validation, shipping and packaging, accelerated aging, and design verification testing. For purposes of establishing substantial equivalence to the Equalizer Occlusion Balloon Catheter, the predicate device was tested for the following using the same methods previously performed on RenovoCath:

- Balloon Inflation Time
- Infusion Flow Rate

RenovoCath underwent additional performance and characterization testing including:

- Determination of extractables/leachables profile after exposure to simulated use conditions (pre-conditioning to simulate expected clinical and infusate properties)
- Evaluation of material changes through functional testing and SEM analysis

The collective results of the testing demonstrate that the RenovoCath meets its specifications and performs as intended. In addition, the bench testing on the predicate device confirms that functionally the Equalizer Catheter and RenovoCath have similar design features to facilitate the delivery of fluids to the peripheral vasculature.

CONCLUSION

The RenovoCath has the same intended use and similar technological characteristics as the Equalizer Occlusion Balloon Catheter predicate device. Functionally, the Equalizer Catheter and RenovoCath have similar design features to facilitate the delivery of fluids to the peripheral vasculature. On this basis, the RenovoCath is substantially equivalent to the predicate device and the indications for use have been updated to reflect the indications for use of the predicate device.

SUMMARY

The RenovoCath is substantially equivalent to the predicate device.