August 23, 2021

RenovoRx, Inc.
Debra Cogan
Director Quality Assurance
4546 El Camino Real, Suite B1
Los Altos, California 94022

Re: K212324
Trade/Device Name: RenovoCath©
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: July 23, 2021
Received: July 26, 2021

Dear Debra Cogan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number
K212324

Device Name
RenovoCath©

Indications for Use *(Describe)*

The RenovoCath 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 is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The RenovoCath is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 3mm to 11mm in diameter.

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

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.

510(k) SUMMARY [per 21 CFR 807.92]

GENERAL INFORMATION

Applicant
RenovoRx, Inc.
4546 El Camino Real, Suite B1
Los Altos, CA 94022
USA
Phone: 1-650-284-4433

Contact Person
Debra Cogan, Director Quality Assurance
RenovoRx, Inc.
Phone: 1-408-515-0820

Date Prepared
July 23, 2021

DEVICE INFORMATION

Trade/Proprietary Name
RenovoCath©

Generic/Common Name
Catheter, Intravascular Occluding, Temporary

Classification
21 CFR§870.4450, Vascular clamp

Product Code
MJN, Catheter, Intravascular Occluding, Temporary

PREDICATE DEVICE

RenovoCath© (K191606)

INDICATIONS FOR USE

The RenovoCath 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 is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug infusion. The RenovoCath is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 3mm to 11mm in diameter.

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

PRODUCT DESCRIPTION

The RenovoCath is a multi-lumen, dual-balloon catheter with a two-part handle that is designed for targeted delivery of fluids, including radiopaque material and therapeutic agents, to selected sites in the peripheral vascular system. The distance between the proximal and distal balloons is adjustable. The effective length is 75cm to 85cm (adjustable). Radiopaque markers are located between the balloons to allow for identification of targeted site and position adjustment under fluoroscopic guidance. The RenovoCath is intended to be used with 6 Fr guide sheaths and 7 Fr guide catheters and is compatible with 0.014" guidewires.

SUMMARY OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS COMPARISON

The indications for use for the RenovoCath are identical to the indications for use for the predicate device. Both devices have the same intended use and technological characteristics. In addition, bench testing confirms that functionally the RenovoCath performs the same as the predicate device in facilitating the delivery of fluids to the peripheral vasculature. The changes impacted the balloon to balloon distance and effective length.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

For the purposes of establishing substantial equivalence to the predicate device, the RenovoCath was tested for the following using the same methods previously established:

- Dimensional Inspection
- Insertion and Tracking Testing
- Balloon Testing
- Infusion Flow Rate Testing
- Simulated In-Vivo Testing

The bench testing confirms that functionally the RenovoCath performs the same as the predicate device in facilitating the delivery of fluids to the peripheral vasculature.

Summary Table Substantial Equivalency

Table 1. Substantial Equivalency Summary

Feature	Predicate Device	Subject Device
	RenovoRx, Inc. RenovoCath K191606	**RenovoRx, Inc.RenovoCath K212324**
Indications forUse	The RenovoCath 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 is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug	The RenovoCath 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 is also indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, and chemotherapeutic drug

Feature	Predicate Device	Subject Device
	RenovoRx, Inc. RenovoCath K191606	**RenovoRx, Inc.RenovoCath K212324**
	infusion. The RenovoCath is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 3mm to 11mm in diameter. The diagnostic and/or therapeutic agents are to be used in accordancewith specifications outlined by the respective agent manufacturer.	infusion. The RenovoCath is intended for general intravascular use in the peripheral vasculature in arteries 3mm and larger. The RenovoCath is intended for use in arteries from 3mm in diameter for vessel entry and to occlude vessels ranging between 3mm to 11mm in diameter. The diagnostic and/or therapeutic agents are to be used in accordance with specifications outlined by the respective agent manufacturer.
Contraindications	It is the responsibility of the physician to determine whether any physical impairment, including any vascular abnormality or reaction to contrast medium, of the patient would contraindicate the use of this device. The RenovoCath is not intended for use in coronary and intracranial arteries. The RenovoCath is not intended for embolic protection or as an aspiration catheter.	It is the responsibility of the physician to determine whether any physical impairment, including any vascular abnormality or reaction to contrast medium, of the patient would contraindicate the use of this device. The RenovoCath is not intended for use in coronary and intracranial arteries. The RenovoCath is not intended for embolic protection or as an aspiration catheter.
Single Use	Yes	Yes
Patient Contacting Materials	Silicone, Pebax, Platinum Iridium	Silicone, Pebax, Platinum Iridium
Effective Length	Adjustable, 76cm-86cm	Adjustable, 75cm-85cm
Sheath Compatibility	6Fr	6Fr
Catheter Size	0.076” (1.93mm) Max diameter	0.076” (1.93mm) Max diameter
Guidewire Compatibility	Long 0.014”	Long 0.014”
Balloon Configuration	Dual: Distal and Proximal	Dual: Distal and Proximal
Balloon Type	Compliant, low pressure	Compliant, low pressure
Balloon Distance	Adjustable, 25mm-120mm	Adjustable, 15mm-109mm
Balloon Occlusion Vessel Range	Proximal and Distal: 3mm-11mm	Proximal and Distal: 3mm-11mm
Recommended Balloon Inflation Volume	0.10cc-1.07cc	0.10cc-1.07cc
Radiopaque Marker	Two markers	Two markers
Sterilization	Ethylene Oxide	Ethylene Oxide

Feature	Predicate Device	Subject Device
	RenovoRx, Inc. RenovoCath K191606	**RenovoRx, Inc.RenovoCath K212324**
Shaft Design	Dual lumen inner shaft within a multi-lumen shaft. One lumen is provided for inflation of the distal balloon in the dual lumen inner shaft and the other is for the guidewire and terminates at the distal tip. The outer catheter is a multi- lumen shaft. One lumen houses the dual lumen inner shaft. A second lumen is provided for proximal balloon inflation. A third lumen is provided for drug infusion.	Dual lumen inner shaft within a multi-lumen shaft. One lumen is provided for inflation of the distal balloon in the dual lumen inner shaft and the other is for the guidewire and terminates at the distal tip. The outer catheter is a multi- lumen shaft. One lumen houses the dual lumen inner shaft. A second lumen is provided for proximal balloon inflation. A third lumen is provided for drug infusion.
Fluid Delivery	Dual Lumen - one lumen for saline delivery and one lumen for infusion of diagnostic or therapeutic fluid.	Dual Lumen - one lumen for saline delivery and one lumen for infusion of diagnostic or therapeutic fluid.
Contrast Medium Ratio	70/30 saline to contrast	70/30 saline to contrast
Accessories	Not applicable; no syringes are included	Not applicable; no syringes are included

CONCLUSION

The RenovoCath has the same intended use and technological characteristics as the predicate device. Functionally, the devices have the same design features to facilitate the delivery of fluids to the peripheral vasculature. The collective results of the testing demonstrate that the RenovoCath meets its specifications and performs as intended. Thus, the RenovoCath is substantially equivalent to the predicate device.