July 9, 2021

RenalPro Medical, Inc.
% Roberta Hines
Regulatory Consultant
Northwest Clinical Research Group, Inc.
19836 NE 125th Place
Woodinville, Washington 98077

Re: K210602
Trade/Device Name: AortaSTAT Occlusion Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: May 29, 2021
Received: June 3, 2021

Dear Roberta Hines:

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,

Rohini Retarekar -S

for Carmen Gacchina Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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 *(if known)*
K210602

Device Name
AortaSTAT Occlusion Device

Indications for Use *(Describe)*
The AortaSTAT Occulsion Device is indicated for temporary vessel occlusion in the suprarenal and infrarenal aorta in applications for perioperative occlusion and emergency control of hemorrhage

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

TRADITIONAL 510(k) SUMMARY

RenalPro Medical, Inc., AortaSTAT Occlusion Device

Submitter: RenalPro Medical, Inc.
2370-B Walsh Avenue
Santa Clara, CA 95051
Phone: (508) 397-6191
Contact Person: Jim Twitchell, Chief Operating Officer

Date Prepared: July 9, 2021

Trade Name of Device: AortaSTAT Occlusion Device

Common or Usual Name: Catheter, Intravascular Occluding, Temporary

Classification Name: Vascular Clamp

Regulatory Class: Class II

Regulation Number: 21 CFR 870.4450

Product Code: MJN

Predicate Device: QXMedical, LLC Occlusion Balloon Catheter (K183679)

Reference Device: Roxwood Medical, Inc. CenterCross Catheter (K140910)

Device Description:

The RenalPro Medical AortaSTAT Occlusion device allows continued distal perfusion of the aorta while occluding the entrance into the target side branch arteries.

The RenalPro Medical AortaSTAT Occlusion Device is comprised of a polymeric thin film membrane covering a self-expanding Nitinol scaffold connected to a stainless-steel central lumen, contained within a stainless-steel braid-reinforced, Pebax outer shaft lined with PTFE for lubricity. The outer shaft and central lumen are attached to a deployment handle. The AortaSTAT Occlusion Device is provided sterile and non- pyrogenic and is for single patient use only.

The AortaSTAT device is delivered to the targeted vasculature location under fluoroscopy using standard endovascular techniques over a commercially available 0.018" Guidewire. Once the device is positioned, the covered scaffold is deployed by actuating the handle to slide the outer shaft back, allowing the scaffold to expand and providing radial occlusion of the target vessel. The AortaSTAT has a radiopaque marker near the distal ends of the nitinol scaffold, and another marker encapsulated at the distal end of the outer shaft to enable visualization under fluoroscopy.

The AortaSTAT device is 8 Fr compatible and is available in four diameters of occluding scaffolds: 19mm, 22mm, 25mm, and 28mm. The device has a 55 ± 5mm occlusive length and a 65cm working length.

Intended Use / Indications for Use

The AortaSTAT Occlusion Device is indicated for temporary vessel occlusion in the suprarenal and infrarenal aorta in applications for perioperative occlusion and emergency control of hemorrhage.

The device is intended for one-time use.

Summary of Technological Characteristics

Like the predicated device, the AortaSTAT is intended for large vessel occlusion in perioperative and emergent hemorrhage cases. Other similarities to the predicate device are percutaneous access via an introducer sheath, the range of sizes including 19mm – 28mm expanded diameter, 8Fr outer catheter diameter, an over-the-wire catheter design, Ethylene Oxide sterilization method, visualization by Platinum-Iridium markers, and some materials such as a Pebax catheter shaft.

The Roxwood Medical CenterCross Catheter cleared under K140910, was identified specifically to support the temporarily expandable and retractable nitinol structure of the AortaSTAT device. The reference device has a Product Code DQY, Percutaneous Catheter. The device also has a handle and central lumen similar to the AortaSTAT device. However, the intended use of the reference device differs from the AortaSTAT as it is intended to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral vasculature.

Performance Data

The AortaSTAT Occlusion Device has undergone design verification and validation testing through a series of physical and mechanical performance tests on the catheter and the covered self-expanding scaffold. Testing was conducted according to applicable US and international standards and guidance documents, including ISO, ASTM, and USP standards, and to applicable internal test methods. FDA-recognized consensus standards were considered for testing.

Testing included: visual inspection/physical dimensions, particulate analysis, scaffold radial force, contrast compatibility, radiopacity, simulated use, torque strength, flexibility and kink resistance, air leak / liquid leak, water entry pressure and burst, tensile strength, shelf life, package integrity, sterilization validation, pyrogenicity, bacterial endotoxin, corrosion resistance, and biocompatibility. Biocompatibility testing included cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, and hemocompatibility. A series of GLP Animal Safety and Performance Studies were conducted to confirm safety and performance of the AortaSTAT in the swine model as compared to the predicate device.

Conclusions

Based on a comparison of the intended use/indications for use, technological characteristics, and the results from a series of non-clinical tests, the AortaSTAT device has demonstrated substantial equivalence to the predicate device.