January 9, 2020

Prytime Medical Devices, Inc
Brian Young
SVP, Quality and Regulatory Affairs
229 North Main Street
Boerne, Texas 78006

Re: K193440
Trade/Device Name: ER-REBOA PLUS Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN, DQY, DQO
Dated: December 5, 2019
Received: December 11, 2019

Dear Brian Young:

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,

for Carmen Gacchina Johnson
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193440

Device Name

ER-REBOA™ PLUS Catheter

Indications for Use *(Describe)*

The ER-REBOA™ PLUS Catheter is intended for temporary occlusion of large vessels and blood pressure monitoring including patients requiring 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.

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K193440

510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Company:	Prytime Medical Devices, Inc. 229 North Main Street Boerne, TX 78006
Contact:	Brian Young SVP, Quality and Regulatory Prytime Medical Devices, Inc. Tel: (210) 340-0116 FAX: (210) 558-1860 Email: byoung@prytimemedical.com

Date Summary Prepared: October 10, 2019

Name of the Device:

Trade Name:	ER-REBOA™ PLUS Catheter
Common Name:	Occlusion balloon catheter
Classification Name:	Vascular clamp
Review Panel:	Cardiovascular (CV)
Regulation:	870.4450, 870.1250, 870.1200
Class:	II
Product Code:	MJN, DQY, DQO

Submission Type: Special 510(k)

Predicate device:

The ER-REBOA™ PLUS Catheter claims substantial equivalence to the ER-REBOA™ Catheter (K172790), manufactured by Prytime Medical Devices, Inc.

Device Description

The ER-REBOA™ PLUS Catheter is a large vessel occlusion catheter. The device consists of an atraumatic distal tip (P-tip®), a compliant occlusion balloon and catheter shaft with a built-in central lumen for blood pressure monitoring. The catheter has a uni-body design and is intended to be placed and advanced without a guidewire. However, the catheter is compatible with straight tipped guidewires up to 0.025" and may be used with a guidewire if desired to facilitate subsequent vascular procedures. The catheter contains two lumens which traverse the length of the catheter and connect to extension lines with stopcocks. The balloon lumen is used to inflate and deflate the balloon. The arterial line lumen is used to monitor blood pressure. Radiopaque marker bands are located on the catheter at the balloon to assist with positioning under fluoroscopy. A peel-away sheath is pre-loaded on the catheter shaft to ease insertion of the catheter's P-tip® into an introducer sheath hemostasis valve.

Principle of Operation

The ER-REBOA™ PLUS Catheter is operated manually to occlude large vessels and monitor blood pressure via an arterial fluid line connection to an external blood pressure monitor.

Indications for Use

The ER-REBOA™ PLUS Catheter is intended for temporary occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhage.

Comparison of Technological Characteristics

Compared to the predicate ER-REBOA Catheter (K172790), the subject ER-REBOA PLUS Catheter is a modified device to enable the catheter to be used with a 0.025" or smaller guidewire, whereas the predicate ER-REBOA Catheter is not guidewire compatible. This modification does not raise different questions of safety and effectiveness and can be evaluated with performance testing.

Performance Data

Risk assessment pursuant to ISO 14971 was performed to assess the impact of the change to enable guidewire compatibility and results of the analysis. The following bench testing was performed: tensile strength; blood pressure; and guidewire compatibility. Testing demonstrated that the changes had the desired effect, i.e., to allow passage of a 0.025" or smaller straight-tip guidewire, but no unintended adverse effects. Accordingly, the results support substantial equivalence of the ER-REBOA™ PLUS Catheter to the 510(k) cleared predicate.

Conclusions

The ER-REBOA™ PLUS Catheter is substantially equivalent to the predicate device.