June 3, 2020

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

Re: K200459
Trade/Device Name: pREBOA-PRO Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN, DQY, DQO
Dated: February 21, 2020
Received: February 25, 2020

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 post-marketing 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 Johnson, Ph.D.
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)*
K200459

Device Name
pREBOA-PRO Catheter

Indications for Use *(Describe)*
The pREBOA-PRO 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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PRYTIME MEDICAL™

The REBOA Company™

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:	June 2, 2020

Name of the Device:

Trade Name:	pREBOA-PRO™ 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: Traditional 510(k)

Predicate device:

The pREBOA-PRO™ Catheter claims substantial equivalence to the ER-REBOA™ Catheter, 510(k) number K172790, manufactured by Prytime Medical Devices, Inc.

Device Description

The pREBOA-PRO™ Catheter is a large vessel occlusion catheter with a dedicated lumen for pressure monitoring. The device consists of a semi-compliant balloon, in-line pressure relief

valve (safety valve), atraumatic distal tip (P-tip™), dual lumen catheter shaft and a hub with extension lines to provide access to each lumen.

The pREBOA-PRO™ Catheter balloon is designed with flow channels to enable the clinician precise, smooth control during inflation and deflation. Instructions for how to titrate the balloon for partial occlusion, if so desired by the clinician, are included in the Instructions for Use.

The device has an effective length of 72 cm and is compatible with 7 Fr introducer sheaths as shown in the compatibility section of the IFU. The catheter has a unibody design and is intended to be placed and advanced without a guidewire. In addition, the catheter is compatible with guidewires up to 0.025" that can be used to facilitate subsequent vascular procedures after a REBOA procedure. A peel-away sheath is preloaded on the catheter shaft covering the balloon to ease insertion of the catheter's P-tip™ into an introducer sheath hemostasis valve. A catheter shaft provides appropriate stiffness with a distal tip (P-tip™) designed for atraumatic advancement of the catheter in a blood vessel. Pad printed marks on both sides of the outer catheter shaft indicate distance to the center of the balloon as well as average insertion depth ranges to the center of aortic Zones 1 and 3 to facilitate proper placement. Radiopaque platinum iridium marker bands are located at the functional ends of the balloon to facilitate and visualize accurate balloon placement when used with imaging. The proximal end of the catheter has a hub and extension lines. The arterial line lumen is used to monitor blood pressure above the balloon. The balloon lumen is used to inflate and deflate the balloon as needed. An in-line Pressure Relief (safety) Valve is connected to the balloon lumen stopcock and is designed to help prevent over-inflation of the balloon. The stopcocks provide control to each of the catheter's two lumens. The peel-away sheath can be separated from the catheter shaft after insertion if needed. The device is a single-use, sterile device.

Principle of Operation

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

Comparison of Technological Characteristics with the Predicate Device

The pREBOA-PRO™ Catheter is identical to the predicate device in terms of intended use and basic technological characteristics. The pREBOA-PRO™ Catheter employs the same basic technologies as the identified predicate including:

- Large Vessel Occlusion with inflatable / deflatable occlusion balloon
- Fluid column pressure monitoring

The pREBOA-PRO™ Catheter has the following differences from the predicate device:

- Guidewire compatibility, including a corresponding P-tip™ change
- Semi-compliant balloon with in-line Pressure Relief (safety) Valve
- Smaller maximum inflation diameter and larger maximum inflation volume
- Longer mounted balloon length

- Improved flow characteristics
- Two-sided outer shaft markings with indication of average Aortic Zone depth

Performance bench and *in vivo* (animal) testing was performed to support the safety and effectiveness of these modifications. The results of these tests demonstrate that the pREBOA-PRO™ Catheter has been designed and tested to conform to its intended use and is comparable to the predicate device. The modifications do not raise different questions of safety and effectiveness, and can be evaluated with performance testing. As such, it claims substantial equivalence to the predicate device.

Performance Data

The following *in vitro* bench tests were performed to demonstrate that the pREBOA-PRO™ Catheter meets applicable design and performance requirements and is therefore equivalent to its predicate device:

- Balloon Burst / Freedom from fragmentation testing
- Balloon inflation / deflation time testing
- Occlusion time testing
- Peel-away sheath peelability testing
- Compatibility testing (Guidewire, Sheath, Catheter Tag, and Luer)
- Torque testing
- Fatigue (inflation/deflation cycle testing)
- Tensile strength testing
- Dimensional testing
- Balloon occlusion volume to inflation diameter testing
- Kink diameter testing
- Freedom from leakage testing
- Printed mark legibility testing
- Pressure relief valve testing (max. pressure and dislodgement)
- Corrosion resistance testing
- Pressure response testing
- Simulated use testing (ex-vivo porcine aorta over-inflation and burst testing)
- Repeatability and reliability testing of flow characteristics (flow loop, Smooth Control Testing)
- Balloon working length characterization testing
- Balloon internal pressure analysis to support Pressure Relief Valve specifications

The following engineering analyses were performed: aortic depth analysis in the target patient population to support zone depth markings on the catheter shaft; and aortic diameter range analysis in the target patient population to support the maximum occlusion capabilities of the pREBOA-PRO™ balloon.

The pREBOA-PRO™ Catheter is categorized as an externally communicating device of limited contact (≤24 hours) with circulating blood, according to ISO 10993-1:2018 and the 2016 FDA Biocompatibility Guidance. Acceptable biocompatibility test results were obtained in accordance with the ISO 10993-1 Standard and FDA Guidance.

The pREBOA-PRO™ Catheter is sterilized by Ethylene Oxide to an SAL of 1×10^{-6}. Sterilization validation was performed in accordance with the recognized consensus standard ANSI AAMI ISO 11135:2014 *Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices*.

The following *in vivo* animal tests were performed to demonstrate that the pREBOA-PRO™ Catheter meets applicable design and performance requirements and is therefore substantially equivalent to the predicate device:

- *GLP Performance Evaluation of the pREBOA-PRO™ Catheter in the Aorta of an Acute Naïve Porcine.*
- *A GLP Thrombogenicity Study in the Ovine Aorta*

Real World Evidence was obtained from a retrospective analysis of data collected from a local prospectively collected database which included consecutive patients who received REBOA for hemorrhagic shock at a major US trauma center between January 2016 and May 2019. Additional data was collected from the patient's medical records. The predicate ER- REBOA™ Catheter was used to perform the REBOA procedures in this study. This data was used to demonstrate feasibility, safety and effectiveness of partial occlusion compared to total occlusion. Corresponding bench and animal test data was used to demonstrate that the pREBOA-PRO Catheter™ is an improved tool allowing clinicians greater ability to control blood flow by the balloon. A brief summary of the study follows:

Initial Clinical Use of Partial Resuscitative Endovascular Balloon Occlusion of the Aorta in a High-Volume Trauma Center.

Clinical Study Summary

Introduction
Resuscitative endovascular balloon occlusion of the aorta (REBOA) is used to temporize patients with infradiaphragmatic hemorrhage. Current guidelines advise <30 minutes, to avoid ischemia/ reperfusion injury, whenever possible. The technique of partial REBOA (P-REBOA) has been developed to minimize the effects of distal ischemia. This study presents clinical experience with P-REBOA, comparing outcomes to complete occlusion (C-REBOA).

Patients and Methods
Retrospective analysis of patients' electronic data and local REBOA registry between January 2016 and May 2019. The Prytime ER-REBOA™ Catheter was used to perform REBOA. Inclusion criteria: adult trauma patients who received Zone I C-REBOA or P-REBOA for infradiaphragmatic hemorrhage, who underwent attempted exploration in the operating room. Comparison of outcomes based on REBOA technique (P-REBOA vs C-REBOA) and occlusion time (>30 min. vs. ≤30 min.).

Results
46 patients were included, with 14 treated with P-REBOA. There were no demographic differences between P-REBOA or C-REBOA. Prolonged (>30 min) REBOA (regardless of type of occlusion) was associated with increased mortality (32% vs 0%, p=0.044) and organ failure. When comparing prolonged P-REBOA with C-REBOA, there was a trend towards lower ventilator days- median (IQR) (19 (11) vs 6 (9); p=0.483) and dialysis (36.4% vs 16.7%; p=0.228) with significantly less vasopressor requirement (72.7% vs 33.3%; p=0.026).

Conclusion
This study demonstrates that REBOA > 30 min. in Zone 1 is associated with increased mortality and need for organ support, while prolonged P-REBOA is associated with less organ failure than C-REBOA. P-REBOA might be a useful tool in safely prolonging REBOA, while avoiding the detrimental consequences of prolonged complete occlusion.

Conclusions

The pREBOA-PRO™ Catheter is substantially equivalent to the predicate device.