DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 4, 2017

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

Re: K170411
Trade/Device Name: ER-REBOA™ Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN, DQY, DQO
Dated: February 8, 2017
Received: February 10, 2017

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. 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.

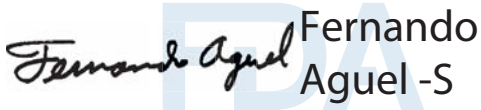
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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)*
K170411

Device Name
ER-REBOA™ Catheter

Indications for Use *(Describe)*
The ER-REBOA™ 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.

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."

5. 510(k) Summary

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

5.1 Submitter Information

Company:

Prytime Medical Devices, Inc.
229 North Main Street
Boerne, Texas 78006 USA
Telephone: 210-340-0116
Fax: 210-558-1860

Contact:

Brian Young
SVP, Quality and Regulatory

229 North Main Street
Boerne, Texas
Telephone: 210-216-3020
Fax: 210-558-1860
byoung@prytimemedical.com

Date Summary Prepared: March 28, 2017

5.2 Name of the Device

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

5.3 Equivalence Claimed to Predicate Device

The ER-REBOA™ Catheter is equivalent to the ER-REBOA™ Catheter (K151821), manufactured by Pryor Medical Devices, Inc. and the Equalizer Occlusion Balloon Catheter (K140273), manufactured by Boston Scientific Corp.

Device Description

The ER-REBOA™ Catheter is a large vessel occlusion catheter with a dedicated lumen for pressure monitoring.

The device consists of a compliant occlusion balloon with an atraumatic distal tip (P-tip®), a dual lumen catheter shaft and a hub with extension lines to provide access to each lumen. The balloon lumen is used to inflate and deflate the balloon. The arterial line lumen is used to monitor blood pressure. The catheter has a uni-body design and is designed to be used without a guidewire. 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. The device has an effective length of 72 cm and is compatible with 7 Fr or larger introducer sheaths. The device is a single use sterile device.

The distal tip (P-tip®) eases advancement of the catheter in a blood vessel. The compliant occlusion balloon is capable of occluding vessels up to 32 mm in diameter. Radiopaque platinum iridium marker bands are located at the functional ends of the balloon to facilitate accurate balloon placement. A co-axial catheter shaft provides appropriate stiffness and a dedicated lumen for pressure monitoring distal to the balloon. Pad printed marks on the outer catheter shaft indicate distance to the center of the balloon to facilitate proper placement. The proximal end of the catheter has a hub and extension lines. 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.

Principle of Operation

The ER-REBOA™ Catheter is operated manually to occlude large vessels and monitor blood pressure.

Intended Use / Indications for Use

Indications for Use: The ER-REBOA™ Catheter is intended for temporary

occlusion of large vessels and blood pressure monitoring including patients requiring emergency control of hemorrhage.

Comparison of Technological Characteristics

The ER-REBOA™ Catheter is identical to the predicate device in terms of technological characteristics. The expiration date is being changed from 1 to 3 years. The labeling changes include minor administrative changes, updated sheath compatibility information, additional options for medical imaging, a clinical data summary, and an update to the indication for use.

The addition of “including patients requiring emergency control of hemorrhage” to the indication for use adds an additional specific indication to the existing general indications for use. The device was designed and intended for situations where emergency hemorrhage is ongoing or expected and this is the most common use of the predicate. Accordingly, the indication change does not alter the intended therapeutic, diagnostic, or surgical use of the device and clinical performance data has demonstrated substantially equivalent safety and effectiveness compared to the predicate device when used as labeled.

Performance Data

Nonclinical Testing
The shelf life extension is supported by test data demonstrating that the device and packaging adhere to the same acceptance criteria used in the original 510(k) after aging equivalent to 3 years.

Clinical Data
Real world clinical data was available for the ER-REBOA™ Catheter and it was derived from: 1) the American Association for the Surgery of Trauma Aortic Occlusion for Resuscitation in Trauma and Acute Care Surgery (AORTA) registry that prospectively identified trauma patients requiring aortic occlusion (AO) from eight ACS Level 1 centers; and 2) a case series report of ER-REBOA™ Catheter use in an austere military environment. All patients were critically injured and required emergency management of hemorrhage. 27.7% of the placements in the registry were without medical imaging and 68.1% of placements in the registry were with plain x-ray. All of the device placements in the case series were performed without medical imaging. Successful aortic occlusion with use of the device was achieved in 95.7% of cases in the registry and with all of the patients in the case series. There were

no instances of extremity ischemia, distal embolism or retroperitoneal hemorrhage as complications of the device.

Conclusions

The ER-REBOA™ Catheter is substantially equivalent to the identified predicate devices.