November 8, 2017

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

Re: K172790
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: September 14, 2017
Received: September 15, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K172790

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.***

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# 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:** | Brian Young<br>SVP, Regulatory and Quality<br>Prytime Medical Devices, Inc.<br>229 North Main Street<br>Boerne, Texas 78006 USA<br>Telephone: 210-340-0116<br>Fax: 210-558-1860<br>byoung@prytimemedical.com |
| **Contact:** | Brian Young<br>SVP, Regulatory and Quality<br>Prytime Medical Devices, Inc.<br>229 North Main Street<br>Boerne, Texas 78006 USA<br>Telephone: 210-340-0116<br>Fax: 210-558-1860<br>byoung@prytimemedical.com |
| **Date Summary Prepared:** | November 6, 2017 |


## 5.2 Name of the Device

| | |
|---|---|
| **Trade Name:** | ER-REBOA™ Catheter |
| **Common Name:** | Occlusion balloon catheter |
| **Classification Name:** | Vascular clamp |
| **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 (K170411), manufactured by Prytime Medical Devices, Inc..

### 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.

## 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 labeling is being modified to remove the pregnancy contraindication, add a warning to protect the fetus if medical imaging is used, and address minor clarifications.

## Performance Data

Clinical Data

Clinical data was provided to demonstrate that the risk of device use during pregnancy doesn't outweigh the reasonably foreseeable clinical benefits. Information supporting removal of the contraindication includes: 1) a clinical rationale that radiation risk of fluoroscopy is not applicable to the ER-REBOA™ Catheter; and 2) a retrospective case series study of 36 patients treated with fluoroscopy-free REBOA for controlling severe postpartum hemorrhage. The REBOA success rate in the case series was 100% and no patients died from REBOA related complications.

## Conclusions

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