



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

October 23, 2015

Pryor Medical Devices, Inc
% Semih Oktay, PhD
President
CardioMed Device Consultants, LLC
5523 Research Park Dr #205
Catonsville, MD 21228

Re: K151821
Trade/Device Name: ER-REBOA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO
Dated: September 22, 2015
Received: September 23, 2015

Dear Dr. Oktay:

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 yours,

Kenneth J. Cavanaugh -S

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151821

Device Name

ER-REBOA Catheter

Indications for Use (Describe)

The ER-REBOA Catheter is intended for temporary occlusion of large vessels and monitoring of blood pressure.

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
PRASStaff@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."



SECTION 07: 510(K) SUMMARY

1 Introduction

- 1.1 The following contains the 510(k) summary for the ER-REBOA™ Catheter. The content of this summary is based on the requirements of 21 CFR 807.92.

2 Applicant Name and Address

Name: Pryor Medical Devices, Inc.

Address: 229 North Main Street
Boerne, TX 78006

Official Contact: Chris Banas, Chairman

Contact Telephone: (210) 340-0116

3 Summary Preparation Date: 07/02/2015

4 Device Name and Classification

Trade Name: ER-REBOA™ Catheter

Common Name: Percutaneous balloon catheter

Classification Name: Percutaneous catheter

Device Classification: Class II, 21 CFR 870.1250

Product Code: DQY, DQO

5 Predicate Devices

- 5.1 The ER-REBOA™ Catheter is claimed to be substantially equivalent to the following devices:
- 5.1.1 Cook Coda Balloon Catheter (K032869), manufactured by Cook Incorporated
 - 5.1.2 Coda LP Balloon Catheter (K150970), manufactured by Cook Incorporated
 - 5.1.3 Cook Pressure Monitoring Catheter (K002254), manufactured by Cook Incorporated

6 Device Description

- 6.1 The ER-REBOA™ Catheter is a large vessel occlusion catheter with a dedicated lumen for pressure monitoring.
- 6.2 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.

- 6.3 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 catheters two lumens. The peel-away sheath can be separated from the catheter shaft after insertion if needed.

7 Principle of Operation

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

8 Intended Use

- 8.1 The ER-REBOA™ Catheter is intended for temporary occlusion of large vessels and monitoring of blood pressure.

9 Comparison of Technological Characteristics

- 9.1 The ER-REBOA™ Catheter is identical in terms of intended use and basic technologic characteristics to the predicate devices. The ER-REBOA™ Catheter employs the same technologies as the identified predicates including:
- 9.1.1 Large vessel occlusion with inflatable/deflatable compliant occlusion balloon
 - 9.1.2 Fluid column pressure monitoring
- 9.2 The ER-REBOA™ Catheter has the following differences from the predicate devices:
- 9.2.1 Use without a guidewire
 - 9.2.2 6 Fr profile (compatibility with a 7 Fr introducer sheath)
 - 9.2.3 72 cm effective length
- 9.3 Performance bench and *in vivo* (animal) testing were performed to support the safety and effectiveness of these modifications. The results of these tests demonstrate that the ER-REBOA™ Catheter has been designed and tested to conform to its intended use and comparably to the predicate devices. Technological differences of the ER-REBOA™ Catheter do not present any new safety or effectiveness concerns. As

such, it can be considered substantially equivalent to the predicate devices.

10 Performance Testing (non-clinical)

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

- 10.1.1 Balloon Burst Testing
- 10.1.2 Balloon Inflation/Deflation Testing
- 10.1.3 Simulated Use Testing
- 10.1.4 Torque Testing
- 10.1.5 Fatigue Testing
- 10.1.6 Occlusion Time Testing
- 10.1.7 Tensile Strength Testing
- 10.1.8 Pressure Response Testing
- 10.1.9 Dimensional Testing
- 10.1.10 Maximum Inflation Volume Testing
- 10.1.11 Balloon Diameter to Inflation Volume Testing
- 10.1.12 Kink Diameter Testing
- 10.1.13 Freedom From Leakage Testing
- 10.1.14 Sterilization Validation
- 10.1.15 Packaging Validation
- 10.1.16 Shelf-Life Validation
- 10.1.17 Biocompatibility Testing

10.2 The following *in vivo* tests were performed to demonstrate that the ER-REBOA™ Catheter meets applicable design and performance requirements and is therefore substantially equivalent to the predicate devices:

- 10.2.1 Performance Evaluation of the ER-REBOA™ Catheter in the Aorta of an Acute Naïve Porcine

11 Conclusions

11.1 Based on a comparison of intended use, the ER-REBOA™ Catheter is substantially equivalent to the identified predicate devices.