



Food and Drug Administration
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February 18, 2016

Bard Peripheral Vascular, Inc.
Ms. Joni Creal
Regulatory Affairs Program Manager
1625 West 3rd Street
Tempe, Arizona 85281

Re: K152136
Trade/Device Name: Recovery Cone[®] Removal System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: December 29, 2015
Received: January 05, 2016

Dear Ms. Creal:

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)

K152136

Device Name

Recovery Cone® Removal System

Indications for Use (Describe)

RC-15 Model: The Recovery Cone Removal System is intended for use to percutaneously remove the Recovery Filter, Recovery G2 Filter and G2 X Filter from the vena cava.

FBRC Model: The Recovery Cone Removal System is intended for use to percutaneously remove the G2 X Filter, G2 Express Filter, G2 Filter and the Recovery Filter from the vena cava, or facilitate the retrieval of foreign objects from the peripheral vascular system.

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.

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**Recovery Cone® Removal System
510(k) Summary**

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-638-2906

Fax: 480-449-2546

Contact: Joni Creal, Regulatory Affairs Program Manager

Date: July 30, 2015

Subject Device Name:

Device Trade Name: **Recovery Cone® Removal System**

Common or Usual Name: Device, Percutaneous Retrieval

Classification: Class II

Review Panel: Cardiovascular Devices

Product Code: MMX

Predicate Devices: Cook FourSnare Vascular Retrieval Snare (K112185)

Device Description:

The Recovery Cone® Removal System is intended to percutaneously remove the G2® X Filter, G2® Express™ Filter, G2® Filter or Recovery® Filter from the vena cava or facilitate the retrieval of foreign objects from the peripheral vascular system. The device is provided sterile and is single use only. The Recovery Cone® Removal System consists of the Removal Cone and Introducer Catheter. The cone consists of a reinforced urethane cone, 15-mm in diameter. The cone is connected to a plastic (Pebax) shaft and handle. The shaft has a central lumen that accommodates a 0.035" guidewire. A Touhy-Borst Y-adapter is used to connect the cone to the Introducer Catheter and to a saline flush or drip. The Introducer Catheter consists of a 10 French

I.D. introducer sheath and dilator. The introducer sheath has a radiopaque marker for enhanced fluoroscopic visualization.

Indications for Use of Device:

RC-15 Model: The Recovery Cone Removal System is intended for use to percutaneously remove the Recovery Filter, Recovery G2 Filter and G2 X Filter from the vena cava.

FBRC Model: The Recovery Cone Removal System is intended for use to percutaneously remove the G2 X Filter, G2 Express Filter, G2 Filter and the Recovery Filter from the vena cava, or facilitate the retrieval of foreign objects from the peripheral vascular system.

Technological Comparison to Predicate Devices:

The technological characteristics of the subject device, Recovery Cone[®] Removal System, are substantially equivalent to the legally marketed predicate device, the Cook FourSnare Retrieval Snare, in terms of intended use, indications for use, operating principle and fundamental scientific technology. Both devices are catheter based systems that have collapsible wires for filter engagement and withdraw into an outer sheath. Both systems are designed to be used over a guidewire. Both devices contain marker bands for visibility. The predicate device contains four wire loops to engage the foreign objects while the Recovery Cone[®] utilized a urethane cone reinforced with wire claws. The predicate wire loop system is designed to advance through a 80cm, 10 French introducer catheter, and the subject device cone is designed to advance through a 75 cm, 10 French I.D. introducer catheter.

Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated using *in-vitro* testing as outlined below. In addition, the ability to capture the filter and retrieve the filter was evaluated in in-vivo animal testing and within clinical references.

- ***In-Vitro – Filter***
 - Tensile

- Leak Test
- Filter Retrieval
- Foreign Body Retrieval
- Sheath and Dilator Tensile, Torque and Leak Integrity Test
- Catheter Simulated Use Test
- Marker Band Integrity
- Filter Removal Force
- ***Biocompatibility, per ISO 10993***
 - Cytotoxicity (ISO 10993-5)
 - Sensitization (ISO 10993-10)
 - Irritation - Intracutaneous Reactivity (ISO10993-10)
 - Acute Systemic Toxicity (ISO10993-11)
 - Pyrogenicity (ISO 10993-11)
 - Hemocompatibility
 - Thromboresistance
 - Coagulation (ISO 10993-4)

In conclusion, the results of these tests provide reasonable assurance that the device is substantially equivalent to the predicate device.