MERIDIAN™ Filter System – Femoral Delivery Kit
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-638-2906
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Contact:	Joni Creal, Regulatory Affairs Specialist II
Date:	September 30, 2011

Subject Device Name:

Device Trade Name:	**MERIDIAN™ Filter System – Femoral Delivery Kit (MD800F)**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Product Code:	DTK
Predicate Devices:	ECLIPSE® Filter System – Femoral Delivery Kit (K101431; Clearance June 24, 2010)
	MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit (K102511; Clearance August 24, 2011)

Summary of Change:

The modifications from the predicate devices, compared to the subject MERIDIAN™ Filter System - Femoral Delivery System, are changes to the delivery system only. The following delivery system components were upsized to accommodate the addition of the

filter arm anchors of the cleared MERIDIAN™ Filter (K102511, August 24, 2011): spline, introducer sheath, introducer hub, introducer hub cap, introducer valve, dilator, dilator hub, dilator marker bands, safety cap and storage tube. All materials are identical, with the exception of the storage tube, which is now polycarbonate tubing with ABS overmold (the predicate storage tube is only polycarbonate tubing). No changes have been made to the MERIDIAN™ Filter as cleared under K102511 on August 24, 2011. Minor changes have been made to the device labeling.

Device Description:

The MERIDIAN™ Filter consists of twelve electropolished shape-memory nitinol wires emanating from a central electropolished nitinol filter hook. These 12 wires form two levels of embolic filtration: the six legs provide the lower level of filtration and the six arms provide the upper level of filtration. The legs contain hooks and the arms contain anchors to resist filter movement. The MERIDIAN™ Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The MERIDIAN™ Filter System – Femoral Delivery Kit consists of a 8 French inner diameter (I.D.) introducer sheath and dilator set, a storage tube preloaded with the MERIDIAN™ Filter and pusher system. The dilator is fitted with 2 radiopaque marker bands spaced 28 mm apart for caval sizing. The introducer sheath contains a radiopaque tip and hemostasis valve with a side port for injecting contrast medium via a syringe. The storage tube and pusher system attach to the introducer and allow for delivery and deployment of the MERIDIAN™ Filter.

Indications for Use of Device:

The subject device, the MERIDIAN™ Filter System – Femoral Delivery Kit, is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Technological Comparison to Predicate Devices:

The technological characteristics of the subject device, the MERIDIAN™ Filter System – Femoral Delivery Kit, are substantially equivalent to those of the predicate devices, in terms of following:

- Intended use (both predicates)
- Indications for use (both predicates)
- Target population (both predicates)
- Operating principle (both predicates)
- Delivery system design (ECLIPSE® Filter System – Femoral Delivery Kit)
- Filter design and material (MERIDIAN™ Filter System – Jugular/Subclavian Delivery Kit)
- Fundamental scientific technology (both predicates)
- Packaging configuration (ECLIPSE® Filter System – Femoral Delivery Kit)
- Sterility Assurance and method of Sterilization (both predicates)

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* and *in vivo* testing performed as outlined below:

In Vitro Delivery System Testing

- Dimensional and Visual Inspection
- Tensile
- Torque
- Flushability
- Component compatibility
- Attachment/Detachment
- Filter Dislodgement

- Pushability
- Trackability
- Removability
- Filter Centering (Tilt)
- Arm and Leg Entanglement (Filter Configuration)
- Deployment Force
- Deployment Accuracy
- Liquid Leakage
- Leakage during power injection
- Burst
- Air Aspiration
- Biocompatibility per ISO 10993-1

***In Vivo* Delivery System Testing**

- Delivery System Trackability and Pushability
- Dilator and Introducer Sheath Trackability and Pushability
- Ease of Deployment (Deployment Force)
- Deployment Accuracy
- Filter Centering (Tilt)
- Arm and Leg Entanglement (Filter Configuration)
- Dilator Marker Band Visibility Under Fluoroscopy
- Introducer Sheath Tip Visibility Under Fluoroscopy

The results from these tests demonstrate that the technological characteristics and performance of the MERIDIAN™ Filter System – Femoral Delivery Kit is comparable to the predicate devices and that the subject device can perform in a manner substantially equivalent to the predicates devices with the same intended use.

Conclusion:

The MERIDIAN™ Filter System – Femoral Delivery Kit is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 24 2011

Bard Peripheral Vascular, Inc.
c/o Ms. Joni Creal
Regulatory Affairs Associate
1625 West Third Street
Tempe, AZ 85281

Re: K112497
Trade Name: Meridian Filter System – Femoral Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: September 30, 2011
Received: October 3, 2011

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram 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): K112497

Device Name: MERIDIAN™ Filter System – Femoral Delivery Kit

Indications for Use:

The MERIDIAN™ Filter System – Femoral Delivery Kit is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

MERIDIAN™ Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112497