

**DENALI® Filter System
510(k) Summary
21 CFR 807.92****MAY 15 2013**

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

Fax: 480-449-2546

Contact: Joni Creal, Sr. Regulatory Affairs Specialist

Date: May 14, 2013

Subject Device Name

Device Trade Name: **DENALI® Filter System –
Jugular/Subclavian Delivery Kit**

Common or Usual Name: Filter, Intravascular, Cardiovascular

Classification: Class II

Classification Panel: Cardiovascular Devices

Product Code: DTK

Predicate Devices: ECLIPSE® Filter System – Femoral and Jugular/Subclavian
Delivery Kit (K101431; Clearance June 25, 2010)

Summary of Change

The ECLIPSE® Filter received FDA clearance under K101431 on June 25, 2010. As part of the product improvement life cycle, Bard Peripheral Vascular, Inc. (BPV) has chosen to re-design its vena cava filter platform. The new filter design is named the DENALI® Filter and incorporates cranial anchors, caudal anchors, penetration limiters and will be terminally electropolished. In addition, minor changes have been made to the IFU.

Device Description

The DENALI® Filter consists of twelve Nitinol appendages emanating from a central snareable tip. These twelve appendages (six legs and six arms) form two levels of filtration for emboli; the legs provide the lower level of filtration and the arms provide the upper level of filtration. Four out of the six legs have cranial anchors and the remaining two legs have caudal anchors. In addition, all of the legs have penetration limiters. The anchors have been designed to resist cranial and caudal migration, while allowing the filter to be percutaneously removed. The DENALI® Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm.

The DENALI® Delivery Systems consist of an introducer sheath and dilator, and a preloaded DENALI® Filter in a storage tube with a pusher. The dilator accepts a 0.035" guidewire and allows for an 800 psi maximum pressure contrast power injection. Radiopaque marker bands are on the end of the dilator to aid in measuring the maximum indicated IVC diameter. They are spaced at a distance of 28 mm (outer-to-outer). The 55 cm, 8.4 French I.D. introducer sheath contains a radiopaque marker band at the distal tip and hemostasis valve with a side port. The pusher advances the filter through the introducer sheath to the pre-deployment mark and is then used to fix the filter in place while the filter is unsheathed.

Indications for Use of Device

The subject device, the DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kits, is indicated for use in the prevention of recurrent pulmonary embolism via 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.

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

Technological Comparison to Predicate Devices

The DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kit has the following similarities to its predicate device, the ECLIPSE® Filter System – Femoral and Jugular/Subclavian Delivery Kit (clearance to market via K101431 on June 25, 2010):

- Same intended use
- Same indications for use
- Similar filter and delivery system design
- Same target population
- Same operating principle
- Same fundamental scientific technology
- Similar packaging configuration and materials
- Same sterility assurance level and method of sterilization

The differences between the subject device and its predicate device are as follows:

- Laser-cut filter from a Nitinol tube (single piece with welded snare tip)
- Caudal anchors
- Penetration limiters (one on each filter leg)
- Dimensional modifications
- Delivery System Modifications
- Updated IFU

The successful completion of the testing required per the risk assessment demonstrates that the technological characteristics and performance criteria of the DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kits are comparable to the predicate device and that the subject device can perform in a manner substantially equivalent to devices currently on the market for the same intended use.

Performance Testing – *In-Vitro* Testing

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated using the *in-vitro* testing as outlined below:

- *In-Vitro - Filter*
 - Fatigue Resistance

- Corrosion Resistance
- Cranial Migration Resistance
- Caudal Migration Resistance
- Penetration Resistance (Radial force)
- Tensile
- Removal Force
- Clot Trapping
- Filter Tip Visibility (Radiopacity)
- MRI Compatibility
- ***In-Vitro – Delivery System***
 - Deployment Force
 - Deployment Accuracy
 - Arm/Leg Entanglement (Configuration)
 - Filter Centering (Tilt)
 - Simulated Use
 - Delivery System Tensile Strength
 - Delivery System Torque
 - Visual Inspection (Freedom from surface defects)
 - Delivery System Visibility (Radiopacity)
 - Dimensional Verification
 - Burst Pressure
- ***Biocompatibility, per ISO 10993 - Filter***
 - Cytotoxicity
 - Sensitization
 - Irritation - Intracutaneous Reactivity
 - Acute Systemic Toxicity
 - Subacute Toxicity and Implantation
 - Genotoxicity
 - Hemocompatibility
- ***Biocompatibility, per ISO 10993 - Delivery System***
 - Cytotoxicity
 - Sensitization
 - Irritation – Irracutaneous Reactivity

- Acute systemic toxicity
- Hemocompatibility

Performance Testing – *In-Vivo* Testing

Two GLP compliant animal studies were performed in support of the DENALI® Filter System, one to assess the filter and one to assess the delivery systems.

To assess the filter, an animal study was performed with the primary objective of the study being to evaluate the retrievability of the DENALI® Filter in an ovine animal model following implantation periods of 4 and 12 weeks. Twelve (12) filter retrievals were evaluated for: 1) ease of removal (as assessed by a clinical evaluator) and 2) cava wall damage as assessed by venography, gross evaluation, and histopathology (in two separate subgroups - immediately post-euthanasia (0 week healing) and after an 8 week healing period). The secondary objectives of this study were to assess caval narrowing/stenosis, caval patency, extravasation, filter strut configuration, filter visibility under fluoroscopy, fracture, intimal irregularities, migration, penetration, perforation, thrombus and tilt.

To assess the delivery systems, an acute animal study in an ovine animal model was performed. The acute study validated the following attributes of 12 Femoral and 12 Jugular/Subclavian DENALI® Filter Systems:

- Dilator Visibility
- Dilator Marker Band Visibility
- Introducer Sheath Tip (Jugular) and Introducer Marker Band (Femoral) Visibility
- Dilator/Introducer Trackability
- Dilator/Introducer Pushability
- Aspiration
- Delivery System Trackability
- Delivery System Pushability
- Ease of Deployment (Deployment Force)
- Deployment Accuracy
- Filter Centering (Tilt)
- Arm/Leg Entanglement

- Filter Visibility Under Fluoroscopy
- Snare Tip Visibility under Fluoroscopy
- Pusher Assembly Visibility Under Fluoroscopy

Based upon the performance assessment, all acceptance criteria were met and the DENALI® Filter System was deemed acceptable by clinical evaluators. Specifically to the retrievability animal study, all 12 filters were successfully removed with an acceptable retrieval force. In addition, based on clinical evaluation and confirmed by the pathologist there was no observed caval occlusion/thrombosis, no definitive IVC penetrations/perforations, no contrast extravasation from the IVC after filter removal, no significant filter tilting, and no hemodynamically significant caval stenosis. One death occurred following filter placement which the pathologist and attending veterinarian determined not to be device related.

The delivery systems were assessed by a clinical evaluator and the following delivery system attributes were found to be acceptable: dilator visibility, dilator marker band visibility, introducer sheath tip (Jugular), introducer markerband (Femoral) visibility, dilator/introducer trackability, dilator/introducer pushability, aspiration, delivery system (with Filter) trackability, delivery system (with Filter) pushability, ease of deployment (Deployment Force), deployment accuracy, filter centering (Tilt), arm/leg entanglement, filter visibility under fluoroscopy, snare tip visibility under fluoroscopy and pusher assembly visibility under fluoroscopy.

Performance Testing – Clinical Testing

A single-arm, prospective, multi-center clinical study was conducted to assess the safety of the DENALI® Filter as both a permanent and retrievable device. Clinical Success Placement (CSP) was defined as freedom from subsequent PE, filter embolization, caval occlusion, filter or procedure related death, insertion adverse events, and technical failure of placement. The pre-established performance goal was that the lower bound of the 95% confidence interval for the CSP was greater than 80%. Technical success of placement (TSP) was defined as deployment of the filter such that the physician judged the location to be suitable to provide sufficient mechanical protection against PE. Additionally, the secondary endpoints of recurrent PE, new or worsening DVT, filter migration, filter fracture and tilt were assessed at the six month visit or the one month post-retrieval visit.

One hundred seventy five (175) patients (107 males, 68 females) were enrolled at 20 investigational sites across the United States. The mean age was 56.7 ± 15.8 years (range 18 – 89 years). Eighty six (86) patients had their filter successfully retrieved.

Of the 175 patients who underwent DENALI® Filter placement, 95 had active thromboembolic disease (the presence of DVT or PE at the time of filter placement). Of these 95 patients, 63 had a contraindication to anticoagulation, 7 had a complication related to the use of anticoagulant medication, 8 had a failure of anticoagulation, and 17 had a filter placed without contraindication, complication or failure related to anticoagulant medication. Eighty (80) patients without active thromboembolic disease (neither DVT nor PE at the time of filter placement) were enrolled in the study.

Reasons for filter placement were as follows: Surgery (n=86, 49%), Trauma (n=41, 23%), Hypercoagulopathy (n=33, 19%), Cancer (n=7, 4%), Stroke (n=3, 2%) and Other (n=5, 3%).

Sixty nine (69) patients completed a six month visit. Longer term data was available in 21 patients at 12-month follow up and in one patient at 18-month follow up. The study will continue to follow all patients to 24 months or 1 month post retrieval, whichever comes first. Three (3) patients withdrew their consent, 3 were lost to follow up and 7 died from pre-existing conditions. An independent Clinical Events Committee (CEC) determined that no patient deaths were attributed to the filter device, or implant or retrieval procedures. This clinical experience will be updated in the IFU once the study is complete.

Table 1: Patient Accountability

	Eligible for Visit (N)	Visit Completed (N, %)	Retrieved	Reason Visit Not Completed				Events Occurring Before Next Visit		Pending Visit
				Death ¹	Lost to Follow-Up	Withdrawn	Missed Visit	Migration	Fracture	
Baseline/Implant	175	175	N/A	0	0	0	0	0	0	N/A
3 Months	128	114 (89%)	28	6	1	0	5	0	0	2
6 Months	88	69 (78%) ²	32	1	1	3	5	0	0	9
12 Months	25	21 (84%) ³	23	0	0	0	1	0	0	3
18 Months	4	1 (25%)	3	0	0	0	0	0	0	3
24 Months	0	0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0
Retrieval	88	88	86	N/A	N/A	N/A	N/A	N/A	N/A	N/A
30 Days Post-Retrieval	86	68 (79%) ⁴	N/A	N/A	1	N/A	N/A	N/A	N/A	8

¹ CEC adjudicated, not device related

² 69 patients completed the 6-month visit, 9 patients were retrieved in the 6-month visit window (6-months plus or minus 30 days)

³ 1 patient was retrieved in the 12-month visit window (12-months plus or minus 30 days)

⁴ 77 patients completed the 30 Day Post-Retrieval Visit, 9 of which occurred during the six month visit window. 68 patients completing the one month post-retrieval visit are reported in the table above to prevent assessment at the 6-month visit and one month post-retrieval visit.

TSP for the DENALI® Filter was 100%. CSP for the DENALI® Filter was 96.1% and the lower bound of the 95% confidence interval was 91.2%. It was concluded that the performance goal was successfully met. Mean placement procedure time was 17.5 minutes.

There were no findings of caval occlusion, filter fracture, cranial migration, caudal migration, filter tilt at placement, or filter tilt at retrieval. There were two (2) cases of symptomatic PE; neither of which caused patient death. There were five (5) cases of asymptomatic penetration; none of which had clinical sequelae. Three (3) cases of penetration were noted at implant and two (2) cases of penetration were noted at retrieval. Twelve (12) patients reported thirteen (13) cases of new or worsening DVT. There were ten (10) cases of new DVT and three (3) cases of worsening DVT. All 10 new DVTs reported were in those patients that had active disease at the time of implant, were considered to be hypercoagulable, or those that had orthopedic procedures on their lower extremities. All site-reported adverse events were adjudicated by the CEC.

Table 2: Complication Rates

Recurrent PE	2 / 139 ¹ (1.4%)
Caval Occlusion	0 / 137 ² (0%)
New DVT	10 / 137 (7.3%)
Worsening DVT	3 / 137 (2.2%)
Filter Fracture	0 / 137 (0%)
Cranial Migration	0 / 137 (0%)
Caudal Migration	0 / 137 (0%)
Filter Penetration at Placement	3 / 175 (1.7%)
Filter Penetration at Retrieval	2 / 88 ³ (2.3%)
Filter Tilt at Placement	0 / 175 (0%)
Filter Tilt at Retrieval	0 / 88 ³ (0%)

¹The denominator of 139 includes 69 patients who completed the 6-month visit, 68 patients who reached the one month post-retrieval visit and 2 patients who had a reported PE outside of the 6-month visit or the one month post-retrieval visit

²All complication rates with a denominator of 137 include 69 patients who completed the 6-month visit and 68 patients who reached the one month post-retrieval visit

³88 patients had a retrieval visit with 86 successful retrievals

DENALI® Filter retrieval was attempted in 88 patients and successful in 86 patients (97.7%). In the two (2) unsuccessful retrieval cases, the snare was unable to engage the filter retrieval hook due to anatomical curvature. Mean filter indwell time was 136.2 ± 90.6 days (median 120.0 days, range 5 – 454 days). The right internal jugular vein was used in all retrieval procedures and mean procedure time was 21.9 minutes.

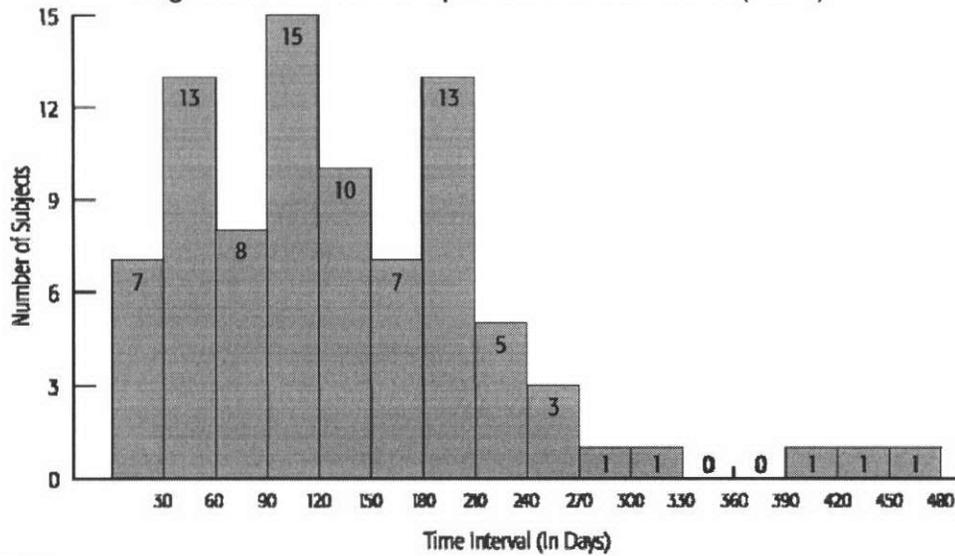
Venacavograms taken before and after the retrieval procedures of the IVC implant site revealed abnormalities that the CEC determined to be related to the device in two patients. One patient had minimal, self limited contrast extravasation post retrieval and another patient experienced intimal injury and caval narrowing of the IVC post retrieval. No clinical sequelae were reported for either patient.

Seventy seven (77) of the 86 patients who had their filter retrieved completed one month follow-up, one (1) subject was lost to follow-up, and eight (8) were pending. No instances of recurrent PE or new or worsening DVT were reported for any patient completing the one month post-retrieval visit.

Table 3: DENALI® Filter Retrieval Details

Number of Filter Retrieval Attempts	88
Number of Successful Retrievals	86
Retrieval Success Rate	97.7%
Mean Indwell Time	136.2 days
Maximum Indwell Time	454 days

Figure 3: Time from Implantation to Retrieval (N=86)



Conclusion

The DENALI® Filter System – Femoral and Jugular/Subclavian Delivery Kits are substantially equivalent to the legally marketed predicate device, the ECLIPSE® Filter System – Femoral and Jugular/Subclavian Delivery Systems (K101431).



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

May 15, 2013

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

Re: K130366

Trade/Device Name: Denali Filter System – Femoral Delivery Kit and Jugular Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: February 14, 2013
Received: February 15, 2013

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 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>. 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 D. Zuckerman -S

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): K130366

Device Name: DENALI® Filter System - Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The DENALI® Filter System - Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via 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.

DENALI® 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 _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman-S
2013.05.15 12:22:13 04'00'