February 29, 2024

BD
Andrew Quach
Senior Regulatory Affairs Specialist
1625 W 3rd Street
Tempe, Alabama 85281

Re: K240257
Trade/Device Name: Denali™ Vena Cava Filter System – Femoral and Jugular/Subclavian Delivery Kit
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: January 30, 2024
Received: January 31, 2024

Dear Andrew Quach:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2024.02.29 12:57:15 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240257

Device Name
Denali™ Vena Cava Filter System – Femoral and Jugular/Subclavian Delivery Kit

Indications for Use *(Describe)*
The Denali™ Filter 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.

The Denali™ Filter may be removed according to the instructions supplied under the Section labeled: Optional Procedure for Filter Removal.

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.

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DENALI™ Filter System
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: 602-830-5680

Fax: 480-449-2546

Contact: Andrew Quach, Senior Regulatory Affairs Specialist

Date: January 30, 2024

Subject Device Name:

Device Trade Name:	**Denali™ Vena Cava Filter System – Femoral and Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Product Code:	DTK

Predicate Devices: (K160866; Clearance April 29, 2016)

Summary of Change:

No changes have been made to the subject Denali™ Filter or Delivery System. The purpose of the submission is to update the IFU for inclusion of the PRESERVE study summary data.

Device Description:

The Denali™ Vena Cava Filter is a venous interruption device designed to prevent pulmonary embolism. The Denali™ Filter can be delivered via the femoral and jugular/subclavian approaches. A separate delivery system is available for each approach. The Denali™ Filter is designed to act as a permanent filter. When clinically indicated, the Denali™ Filter may be percutaneously removed after implantation according to the instructions provided under the "Optional Procedure for Filter Removal" section in the Instructions for Use.

The Denali™ Filter consists of twelve shape-memory laser-cut nickel-titanium appendages. These twelve appendages form two levels of filtration with the legs providing the lower level of filtration and the arms providing the upper level of filtration. The Denali™ Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28mm.

The Denali™ Vena Cava Filter System consists of an introducer sheath, an 8 French dilator, and a preloaded Denali™ Filter in a storage tube with a pusher. The 8 French dilator accepts a 0.035" guidewire and allows for an 800 psi maximum pressure contrast power injection. Radiopaque marker bands on the end of the dilator aid in measuring the maximum indicated IVC diameter. They are spaced at a distance of 28mm (outer-to-outer). The 55cm, 8.4 French I.D. introducer sheath contains a radiopaque marker and hemostasis valve with a side port. The pusher advances the filter through the introducer sheath to the predeployment mark and is then used to fix the filter in place while the filter is unsheathed.

Indications for Use of Device:

The Denali™ Filter 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.

The 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 technological characteristics of the subject device, the Denali™ Filter System - Femoral and Jugular/Subclavian Delivery Kit, are identical to those of the predicate devices, in terms of the following:

- Identical Intended use
- Identical Indications for use
- Identical target population
- Identical delivery system design
- Identical filter design and material
- Identical fundamental scientific technology
- Identical packaging configuration
- Identical Sterility Assurance and method of Sterilization

Performance Testing Summary:

No new operating principles have been introduced with the subject device. The subject Denali™ Filter System - Femoral and Jugular/Subclavian Delivery Kit operates using the same fundamental scientific technology as the predicate Denali™ Filter System - Femoral and Jugular/Subclavian Delivery Kit. Therefore, no performance testing was performed. The clinical testing was previously provided to FDA under the Investigational Device Exemption.

Conclusion:

The Denali™ Filter System - Femoral and Jugular/Subclavian Delivery Kit is substantially equivalent to the legally marketed predicate device. No changes have been made to the device or delivery system. The only changes being made are to add the PRESERVE summary results to the Instructions For Use.