DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 26, 2016

B.Braun Interventional Systems Inc.
Peter Flosdorf
Engineering Manager
824 Twelfth Avenue
Bethlehem, Pennsylvania 18018

Re: K152765
Trade/Device Name: VenaTech Convertible Vena Cava Filter System
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: December 30, 2015
Received: December 31, 2015

Dear Mr. Flosdorf:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152765

Device Name
VenaTech® Convertible™ Vena Cava Filter System

Indications for Use *(Describe)*
The VenaTech® Convertible™ Vena Cava Filter System is indicated for 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 in thromboembolic diseases;
• Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
• Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

When clinically indicated after implantation, the VenaTech Convertible filter can be converted to an open configuration to discontinue filtration according to the 'Conversion Procedure' in the Instructions for Use.

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.

510(K) SUMMARY

Date Prepared: February 25, 2016

510(k) Submitter	Contact
B. Braun Interventional Systems Inc. 824 Twelfth Avenue Bethlehem, PA 18018 FDA Est. Reg. #: 3006332832	Contact: Peter Flosdorf, Engineering Manager Tel: 610-997-4694; Fax: 610-849-5319 Peter.Flosdorf@bbraunintervention al.com

General Information	
Trade Name	VenaTech® Convertible™ Vena Cava Filter System
Common Name	Vena cava filter system
Classification Information	Cardiovascular Intravascular Filter (21 CFR 870.3375; Class II) ProCode: DTK; Panel: Cardiovascular
Predicate	VenaTech LP Vena Cava Filter System (K010485, K063217)
Reference Device	VenaTech LGM Vena Cava Filter System (K881604, K901454, K925679, K932921)

Device Description

The VenaTech Convertible Vena Cava Filter is a flexible, symmetrical, cobalt-chromium metal alloy, self-expanding vena cava filter intended for permanent implantation into the infrarenal inferior vena cava to provide protection against pulmonary embolism. When clinically indicated, the clot-trapping features of the VenaTech Convertible filter can be deactivated by percutaneously converting the filter to an open configuration. The VenaTech Convertible filter is pre-loaded in a cartridge (syringe) and provided as a system with introducer accessories and instructions to accommodate delivery and implantation either using the femoral or jugular approach.

Intended Use / Indications

The VenaTech® Convertible™ Vena Cava Filter System is indicated for 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 in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

When clinically indicated after implantation, the VenaTech Convertible filter can be converted to an open configuration to discontinue filtration according to the 'Conversion Procedure' in the Instructions for Use.

Substantial Equivalence Comparison

The VenaTech Convertible Vena Cava Filter System has substantially equivalent indications and principle of operation to the currently marketed VenaTech LP predicate system. The VenaTech Convertible filter design, materials, introducer accessories, sterile package configuration, and sterilization process are substantially similar when compared to the currently marketed predicate filter. The VenaTech Convertible system has design features that permit the filter elements to convert to an open configuration when clinically indicated to no longer trap emboli. Like the predicates, the VenaTech Convertible filter is intended for permanent implantation and is not to be removed following implantation.

Performance Data

Non-clinical Evaluations (Bench)

The VenaTech Convertible system has been evaluated through ISO 14971-compliant risk analysis and design verification and validation (DV&V) testing in accordance with ISO 25539-3 Cardiovascular implants – Endovascular devices – Part 3: Vena cava filters and in consideration of the FDA guidance for cardiovascular intravascular filter 510(k) submissions. Results from the DV&V testing, which was completed both on the bench and in animals, shows the VenaTech Convertible filter is sufficiently robust for its intended use as a permanent vena cava filter and demonstrates the mechanical integrity and performance of the filter's convertible feature. The ISO 25539-3 compliant DVT included the below evaluations:

- Cavography ability
- Clot trapping test
- Conversion force
- Dilator spinlock resistance
- Dimension of introduction system
- Fatigue resistance (fracture, cracks, and corrosion)
- Filter dimension
- Filter head resistance
- Filter radio-opacity
- Filter welding resistance
- Head assembly resistance
- Hook crimping strength
- Introduction sheath radio-opacity
- Introduction system traction resistance
- Introduction sheath water tightness
- Migration resistance
- (Packaging) Transportation
- (Packaging) Fall (drop)
- Passage in sheath
- Radial force
- Radial pressure (contact pressure)
- Magnetic resonance (MR) testing

Additionally, the VenaTech Convertible filter was subjected to chemical characterization evaluations performed in accordance with ISO 10993 Biological Evaluation of Medical Devices - Part 18: Chemical characterization of materials.

Animal Studies

Simulated use testing was performed in a sheep model. Results of this animal testing demonstrated that the VenaTech Convertible filter performed according to its intended use, and thus supports substantial equivalence.

Clinical Evaluation

A multi-center, prospective, single-arm, historical (literature) controlled clinical study was performed to evaluate the VenaTech Convertible filter safety and performance in a minimum of 75 subjects in whom the filter has been implanted, converted and followed for 6-months. Converted subjects were followed at 30-days, 3-months, and 6-months post conversion. Subjects that were unable to undergo conversion (due to clinical condition based on investigator discretion) were followed at 6-months post filter implant (these subjects are referred to as 'permanent filtration subjects'). In this study, eleven (11) sites enrolled a total of 149 subjects. The VenaTech Convertible filter was successfully implanted in all 149 subjects. There were 96 attempted conversions of the filter, 93 actual conversions, and 89 successful conversions with no technical complications. The primary objective, technical success, was achieved in 92.7% of subjects, therefore the primary objective was met. Refer to the IFU for clinical study information.

Conclusions

The VenaTech Convertible Vena Cava Filter System is similar in indications, principle of operation, and design to the currently marketed VenaTech LP Vena Cava Filter System predicate. The few design differences, which allow the filter to be converted to no longer trap emboli, were subjected to non-clinical and clinical performance evaluations in accordance with FDA guidance and industry standards. Based on the predicate comparison and performance evaluation information provided in this 510(k), it can be concluded that the VenaTech Convertible Vena Cava Filter System raises no new questions of safety or effectiveness compared to the predicate devices and is, therefore, substantially equivalent.

- End of 510(k) Summary -