510(k) Summary

JAN 12 2007

as required by section 807.92(c)

Date Prepared: October 17, 2006

1. Submitter's Name / Contact Person

Submitter Name
B. Braun Medical, Inc.
824 Twelfth Avenue
Bethlehem, PA 18018

Contact Person
Paul O'Connell
Vice President, Vascular Interventional Products Group
Tel: (847) 274-0097; Fax: (847) 733-1669

2. General Information

Trade Name	VenaTech™ LP Brachial Introducer System (Antecubital) *for use with the* VenaTech™ LP Vena Cava Filter
Common Name	Permanent Vena Cava Filter Introduction System
Classification Name	The VenaTech™ LP Vena Cava Filter is classified as a Cardiovascular Intravascular Filter pursuant to 21 CFR 870.3375. The VenaTech™ LP Brachial Introducer System (Antecubital) is an accessory to the VenaTech™ LP Vena Cava Filter.
Predicate Devices	B. Braun Medical Inc. – VenaTech LP Vena Cava Filter Cordis Corporation – Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit

3. Device Description

The VenaTech™ LP Brachial Introducer System (Antecubital) allows for placement of the VenaTech LP Vena Cava Filter by an antecubital vein approach. The antecubital introducer system consists of an introducer sheath and dilator, guidewire, and pusher components. The introducer system is provided sterile.

4. Intended Use / Indications

The VenaTech™ LP Brachial Introducer System (Antecubital) is intended for use with the B. Braun Medical VenaTech™ LP Vena Cava Filter.

5. Substantial Equivalence Comparison

The addition of the VenaTech LP antecubital introducer system for use as an accessory with the VenaTech LP Vena Cava Filter has not changed the intended use of the previously cleared VenaTech LP Vena Cava Filter. The VenaTech LP Filter design, materials, sterile package configuration, and sterilization process are identical to the currently marketed VenaTech LP Filter

predicate device. The fundamental scientific technology of the VenaTech LP Filter has not been altered nor have new questions of safety and effectiveness been raised. Dimensional changes in the length of the introducer, guidewire, and long pusher were made to accommodate the antecubital delivery approach.

Antecubital delivery of a vena cava filter is not new, the Cordis TrapEase™ Permanent Vena Cava Filter and Introduction Kit also accommodates an antecubital delivery approach.

The antecubital introducer system has been evaluated through risk analysis and design verification testing following established Design Control procedures. The addition of the VenaTech LP Brachial Introducer System (Antecubital) as an accessory to the VenaTech LP Vena Cava Filter raises no new questions of safety or effectiveness.

6. Summary of Non-Clinical Testing

Confirmatory design verification testing was performed and demonstrates that the VenaTech LP Filter can reliably be delivered and deployed through the VenaTech™ LP Brachial Introducer System (Antecubital).

- The remainder of this page intentionally left blank.-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2007

B. Braun Medical, Inc.
c/o Paul O'Connell
824 Twelfth Avenue
Bethlehem, PA 18018

Re: K063217
Trade/Device Name: VenaTech™ LP Brachial Introducer System (Antecubital) for use with the VenaTech™ LP Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: October 17, 2006
Received: October 24, 2006

Dear Mr. O'Connell:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K063217

Device Name:

VenaTech™ LP Brachial Introducer System (Antecubital)

Indications for Use:

The VenaTech™ LP Brachial Introducer System (Antecubital) is intended for use with the B. Braun Medical VenaTech™ LP Vena Cava Filter.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063217

(Posted November 13, 2003)