

K133681

510(K) SUMMARY

JAN 30 2014

SPONSOR: Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670

CONTACT/SUBMITTER: Elisa Hebb
Sr. Director Clinical Development
Volcano Corporation
Tel: 858-720-4184

DATE OF SUBMISSION: November 27, 2013

DEVICE: Percutaneous Retrieval Device

Trade Name: Crux® Snare Filter Retrieval Set

Common Name: Vena Cava Filter Retrieval Set

Product Code: MMX

Classification: 21 CFR 870.5150
Class II Device

PREDICATE DEVICE: Günther Tulip Vena Cava Filter Removal Set (K073374)

Reference Device: Cook FourSnare Vascular Retrieval Snare (K112185)

DEVICE DESCRIPTION: The Crux® Snare Filter Retrieval Set consists of a 0.035" PTFE-coated guidewire, 18 gauge introducer needle, 8.2 F inner sheath with dilator, 10 F outer sheath, Crux Snare, introducer and torque tool. The components are designed to be used percutaneously to retrieve the Crux Vena Cava filter via either the jugular or femoral vein approach.

INTENDED USE: The Crux® Snare Filter Retrieval Set is an endovascular medical device indicated for the retrieval of the Crux® Vena Cava Filter (VCF) percutaneously via the jugular vein or femoral vein approach.

COMPARISON OF CHARACTERISTICS:

The Crux® Snare Filter Retrieval Set, its predicate and reference device are intended for the retrieval of vena cava filters. The subject and predicate devices are delivered via conventional venous access through dilators and flexible, coaxial polymeric catheters—sheaths— over a 0.035" guidewire, to the filter's retrieval tail. Radiopaque features on the sheaths and snare provide the physician with visibility during angiography. The sheath/snare assembly is advanced to a position close to the filter's retrieval tail, and then the inner sheath, enclosing the snare, is advanced independently to an even closer position. The snare is advanced out of the inner sheath so that it can engage the filter. When the snare is appropriately positioned, the inner sheath is advanced to engage the filter (Crux) or, the snare is withdrawn into the sheath (predicate). The outer sheath is then advanced over the snare that has trapped the filter retrieval tail. The outer sheath is further advanced, collapsing and capturing the filter. The entire assembly is then withdrawn.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the device. Bench testing was conducted against known standards, product specification, or against the predicate device and evaluated the following: Visual; Dimensional; Hemostasis/Flushing/Compatibility; Radiopacity; Ability to access; and Bond Tensile.

Biocompatibility testing was conducted on the device and the following tests were successfully completed:

- Cytotoxicity
- Hemocompatibility, including
 - Hemolysis, ASTM Method, extract (human blood)
 - Hemolysis, direct contact (ASTM)
 - Partial Thromboplastin Time (PTT)
 - Complement Activation, both 3Ca and SC5b-9
 - Platelet and Leukocyte Count – PLC
 - Thrombogenicity (Sheep)
- Sensitization
- Irritation
- Systemic Toxicity, including
 - Systemic Injection (ISO)

- Material Mediated Pyrogenicity

Conclusion

Completion of these tests concluded that the proposed Crux Snare Filter Retrieval Set is substantially equivalent to the predicate device and reference device.



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

January 30, 2014

Volcano Corporation
Ms. Elisa Hebb
Senior Director, Clinical Development - Peripheral Vascular
2870 Kilgore Road
Rancho Cordova, CA 95670

Re: K133681
Trade/Device Name: Crux Snare Filter Retrieval Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Device, Percutaneous Retrieval
Regulatory Class: Class II
Product Code: MMX
Dated: November 27, 2013
Received: December 2, 2013

Dear Ms. Hebb:

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" (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 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 D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K133681

Device Name Crux® Snare Retrieval Set

Indications for Use

The Crux® Snare Filter Retrieval Set is an endovascular medical device indicated for the retrieval of the Crux® Vena Cava Filter (VCF) percutaneously via the jugular vein or femoral vein approach.

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over the Counter Use _____

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Bram D. Zuckerman -S
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