**510(k) Summary**
Crux Vena Cava Filter System
21 CFR 807.92

**Device Common Name:** Vena Cava Filter

Crux Biomedical, Inc.
1455 Adams Drive, #1170
Menlo Park, CA USA 94025
Tel: 650-321-9903
Fax: 650-321-9904

Elisa Hebb
Vice President, Clinical and Regulatory Affairs
Crux Biomedical, Inc.

**Correspondent Contact Information:**
1455 Adams Drive, #1170
Menlo Park, CA 94025
Tel: 650-321-9903
Fax: 650-321-9904
Email: ehebb@cruxbiomedical.com

**Device Classification Regulation & Name:**
21 CFR 870.3375, Cardiovascular intravascular filters

**Device Classification & Product Codes:**
Class II, DTK

**Panel:**
Cardiovascular

**Prior FDA Document Numbers:**
G070035/S001 through G070035/S032

**Device Proprietary Name:** Crux Vena Cava Filter System

**Basis of Submission:**
New Device

**Kit Description:**
Crux Vena Cava Filter System consists of:
- Crux Vena Cava Filter
- Crux Delivery Catheter
- 7014 – Crux Vena Cava Filter System – Femoral
- 7015 – Crux Vena Cava Filter System - Jugular

**Intended Use**
The Crux VCF System is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava (IVC) 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
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Crux VCF may be removed according to the instructions contained in the Instructions for Use section “Optional Retrieval of the Crux VCF” in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

Device Description – Crux Vena Cava Filter (VCF) System

The Crux VCF System is an endovascular medical device used in the prevention of recurrent pulmonary embolism (PE). The system consists of a self-expanding Nitinol filter delivered from a single-use, disposable 9Fr catheter, which can be used percutaneously to deploy the filter. The filter wireforms are composed of two opposing self-expanding Nitinol spiral elements connected at each end with Nitinol crimps. One end of each wireform is formed into a sinusoidal shaped retrieval tail to aid in retrieval of the filter using a snare. Each retrieval tail has an atraumatic plasma ball and a radiopaque tantalum marker band to facilitate visualization. There are five tissue anchors attached to the wireforms elements with Nitinol tubing. The filter is designed to treat IVC diameters of 17 to 28mm.

The delivery catheter for the Crux VCF is a disposable, 9Fr introducer-sheath-compatible, single-use delivery catheter. The filter is provided loaded in the Crux VCF System for jugular or femoral approach delivery. The delivery catheter is an over-the-wire system, 0.035” guidewire-compatible, and consists of a polycarbonate inner shaft and a nylon outer shaft. The inner shaft consists of the guidewire lumen and a flexible, radiopaque tracking tip. The outer shaft has a radiopaque distal marker band, a Touhy-Borst hemostasis valve and a one-way checkvalve for flushing.

The filter can be retrieved with commercially available snares and sheaths via either the jugular or femoral approach.

Predicate Device Information

Predicate Device: Option Vena Cava Filter

510(k) Numbers: K081410
Comparison to Predicate Device
Both the Crux VCF System and predicate device share similar designs, mode of operation and materials. Both filters are delivered to the vena cava via transcatheter approach. When deployed, the nitinol material utilized in both the predicate and subject devices allows for self-centering of the filter. Both filters are designed with anchors to secure the filter to vessel wall and both filters can be safely retrieved via catheterization.

The primary differences between the predicate and subject devices are the filter geometry and the addition of ePTFE filter web incorporated in the Crux VCF design. Based on the design verification and validation results, the variation in geometry and addition of the ePTFE filter web do not have an adverse impact on the safety and effectiveness of the VCF when compared to the predicate device.

As demonstrated in the results of the clinical trial, these differences in design do not adversely affect the clinical outcomes when compared to the predicate device and the devices are substantially equivalent.

Other areas of substantial equivalence with predicate device:
Intended Use
Indications for Use
Target Patient Population
Mode of Operations

Summary of Supporting Data
Performance testing was conducted to establish substantial equivalence to the predicate device as outlined below:

In vitro testing
   Biocompatibility
   Shipping and Packaging
Dimensional and Visual Inspection
Deployment
Retrievability
Trackability
Deployment
Radial Force
Bond and Torque Strength
MRI Compatibility
Clot Trapping
Fatigue
Corrosion

In vivo testing (Pre-clinical)
Deployment
Retrieval
Positional Stability
IVC histopathology

Clinical Testing Summary:
A clinical trial was conducted under an approved IDE and IRB protocol to further establish the safety, effectiveness and substantial equivalence to the predicate device. One hundred and twenty-five (125) subjects with a temporary or permanent risk of recurrent pulmonary embolism were enrolled into a prospective, single arm, multinational clinical trial. Subjects were followed for 180 days or 30 days after filter retrieval. The primary endpoint of clinical success is defined as technical success of deployment and freedom from PE, filter migration, and device related adverse events requiring intervention. Secondary endpoints include retrieval success, filter migration, IVCF thrombosis, and device integrity.

The technical success rate was 123/125 (98%). There were 3 cases of recurrent PE (2.4%) and no cases of embolization, migration or fracture. There were 8 cases of asymptomatic, new inferior vena cava (IVC) thrombus including 5 observed at retrieval evaluation. Clinical Success was 96% (91.8% lower one-sided 95% CL exceeding the 80). Retrieval success was 53/54 (98%) at a mean of 83 ± 57 days (range 7 to 190) with 1 radiographic anomaly observed with no clinical sequelae.
The clinical trial demonstrated the safe deployment, implant and retrieval of the filter. Technical and retrieval success are high, with a low rate of device related complications.

**Conclusion:**
Bench test, animal test and the clinical trial results demonstrate that the device meets the established success criteria and is substantially equivalent to the predicate device.
Crux Biomedical, Inc.  
c/o Ms. Elisa Hebb  
Vice President, Clinical and Regulatory Affairs  
1455 Adams Drive, #1170  
Menlo Park, CA 94025

Re: K120402  
Trade/Device Name: Crux Vena Cava Filter System  
Regulation Number: 21 CFR 870.3375  
Regulation Name: Cardiovascular intravascular filter  
Regulatory Class: Class II  
Product Code: DTK  
Dated: July 9, 2012  
Received: July 10, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFices/uecil15809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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,

M. A. 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: This application  K120402

Device Name: Crux Vena Cava Filter System

Indications For Use:

The Crux VCF System is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava (IVC) 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
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Crux VCF may be removed according to the instructions contained in the section “Optional Retrieval of the Crux VCF” in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120402