



February 17, 2017

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Novate Medical Ltd.
Gordon Crowley
Regulatory & Quality Director
Block 11, Galway Technology Park, Parkmore
Galway, Ireland

Re: K162875
Trade/Device Name: Sentry Inferior Vena Cava Filter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: January 17, 2017
Received: January 19, 2017

Dear Gordon Crowley:

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,



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)

K162875

Device Name

Sentry Inferior Vena Cava Filter

Indications for Use (Describe)

The Sentry IVC Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in patients with a transient high risk of PE, 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.

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.

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510(k) Summary

Date Prepared: February 13, 2016

510(k) Submitter: Novate Medical Ltd., Block 11, Galway Technology Park,
Parkmore, Galway, Ireland.

Contact: Gordon Crowley, Quality and Regulatory Director

Tel: +353 91 787716

Trade Name: Sentry Inferior Vena Cava Filter

Common Name: Vena Cava Filter

Classification Information: Cardiovascular Intravascular Filter (21 CFR 870.3375; Class II)

Product Code: DTK

Panel: Cardiovascular

Predicate Devices: Cordis Optease® IVC Filter (K034050)

B.Braun VenaTech Convertible IVC Filter (K152765)

The Sentry IVC Filter is a bioconvertible IVC filter intended for percutaneous implantation in the IVC and designed to provide protection against PE in patients at transient risk of PE.

The Sentry IVC Filter is designed for use in inferior vena cavae with diameters between 16mm and 28mm and has a maximum deployed length of 57.7mm. It is preloaded in a Loading Tool that can be orientated for either left/right femoral vein or a right jugular vein approach and is delivered through a 7 French ID Introducer Sheath (max OD 9.75Fr).

The Sentry IVC Filter consists of a cylindrical Nitinol frame and a Filter Cone formed by 6 Filter Arms held together in the center of the IVC by means of a bioabsorbable filament. The Filter Cone that is designed to trap emboli and thereby reduce the risk of PE while maintaining caval patency after it has converted. The Sentry IVC Filter converts into a non-filtering configuration, the Filter Cone opens and the arms retract towards the IVC wall.

Intended Use / Indications

The Sentry IVC Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in patients with a transient high risk of PE, 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.

Substantial Equivalence Comparison

The Sentry IVC Filter is substantially equivalent in its intended use, principles of operation, design, materials, and sterile package configuration to the Cordis OptEase Vena Cava Filter (K034050) and the B.Braun VenaTech Convertible IVC Filter (K152765). The Sentry IVC Filter is designed to bioconvert from a Filtering Configuration to a Non-Filtering Configuration. The design differences, which allow the Filter to convert to the non-filtering configuration, were subjected to non-clinical and clinical performance evaluations.

Performance Data

Novate developed a design verification and validation program for the Sentry IVC Filter with reference to the *FDA Guidance for Cardiovascular Intravascular Filter 510(k) Submissions* and the international standard ISO 25539-3 *Cardiovascular implants- Endovascular devices -Part 3: Vena cava filters*. Bench and animal studies were

undertaken to demonstrate the performance and safety of the Sentry IVC Filter when used according to the Instructions for Use.

The design verification and validation program included the evaluations listed below:

• Delivery System visual and dimensional	• Clot Trapping Efficiency
• Delivery System integrity	• Migration resistance
• Filter visual and dimension	• Magnetic resonance testing
• Filter radio-opacity	• Filter Migration Pressure
• Fatigue resistance	• Radial Force
• Filter Corrosion	• Ease of device use
• Packaging Visual Inspection	• Filter Time-to-Opening
• Labeling Visual Inspection	• Simulated Deployment
• Tyvek Pouch Peel	• Accuracy of Deployment
• Foil Pouch Peel	• Finite Element Analysis
• Bubble Leak Testing	• Computational Flow Dynamics
• Transportation testing	

All tests met the pre-determined acceptance criteria. Results from the design verification and validation program demonstrate the Sentry IVC Filter achieves its intended use as a vena cava filter and demonstrates the mechanical integrity and performance of the device.

Biocompatibility Evaluations

A biological safety assessment was performed to evaluate the biological risks associated with the Sentry IVC Filter per FDA's *Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*. This risk assessment involved biocompatibility testing on the implant and delivery system/accessories. The Sentry IVC Filter was also subjected to chemical characterization evaluations performed in accordance with *ISO 10993 Biological Evaluation of Medical Devices - Part 18: Chemical characterization of materials*. The biocompatibility studies, required by *ISO 10993 Biological Evaluation of Medical Devices - Part 1: Evaluation and testing* were performed in accordance with Good Laboratory Practices (GLP; 21 CFR Part 58).

Animal Studies

GLP animal studies were performed in an ovine model during the development of the Sentry IVC Filter. A predicate device (Cordis OptEase IVC Filter [K034050]) was also evaluated as a control and comparison. Results of this animal testing demonstrated that the Sentry IVC Filter performed according to its intended use, and thus support the safety of the Sentry IVC Filter.

Clinical Evaluation

A prospective, multi-center, single-arm clinical study with a performance goal was conducted to assess the safety and effectiveness of the Sentry IVC Filter. A total of 129 subjects were enrolled at 23 investigational centers. Subjects were evaluated at 1 month, 2 months and 6 months. The primary composite endpoint of Clinical Success at 6 months comprising: technical success; freedom from symptomatic PE; and freedom from IVC filter-related complications to 6 months was achieved in 97% of subjects; therefore the primary objective, Clinical Success, was met. There was no incidence of symptomatic PE, Filter tilting, Filter migration, Filter embolization, Filter fracture, Filter perforation or Filter-related death at the 1 month, 2 months and 6 month follow-ups. Refer to the IFU for clinical study information.

Conclusions

The Sentry IVC Filter is similar in indications, principle of operation, and design to the currently marketed Cordis OptEase IVC Filter (K034050) and B.Braun VenaTech Convertible IVC Filter (K152765). The design differences, which allow the Sentry IVC Filter to convert to the non-filtering configuration, were evaluated by non-clinical and clinical performance studies. Based on the supportive data provided in this 510(k), it can be concluded that the Sentry IVC Filter raises no new questions of safety or effectiveness compared to the predicate devices and is, therefore, substantially equivalent.