June 6, 2018

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

Re: K181202
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: May 4, 2018
Received: May 7, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181202

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 **K181202**

Date Prepared:	May 4, 2018
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 Device:	Sentry IVC Filter (K173236)

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 six Filter Arms held together in the center of the IVC by means of a bioabsorbable filament. The Filter Cone 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.

This 510(k) is submitted to support a change to the design and manufacturing process for the Introducer Sheath of the Delivery System.

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 modified Sentry IVC Filter is substantially equivalent to the cleared Sentry IVC Filter (K173236). There is no change to the fundamental scientific technology or to the intended use.

The primary difference between the predicate and modified device is the design and manufacturing process for the Introducer Sheath of the Delivery System.

Based on a risk assessment and design verification results, the modification does not have an adverse impact on the safety or effectiveness of the modified device when compared to the predicate device.

Performance Data

Novate developed a design verification program for the modified Sentry IVC Filter. Bench studies were undertaken to demonstrate equivalent performance of the modified Sentry IVC Filter when used according to the Instructions for Use. The design verification program included the following evaluations:

- Introducer Sheath integrity
- Introducer Sheath patency

All tests met the pre-determined acceptance criteria. Results from the design verification program demonstrate the mechanical integrity and performance of the modified device.

Conclusions

The modified Sentry IVC Filter is identical in intended use to the currently cleared Sentry IVC Filter (K173236). There is no change to the principles of operation or fundamental scientific technology. The change to the design and manufacturing process for the Introducer Sheath does not raise different questions of safety and effectiveness. Based on a risk assessment and design verification testing, the data supports that the modified Sentry IVC Filter is substantially equivalent to the predicate device.