February 22, 2018

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

Re: K173236
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 23, 2018
Received: January 25, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*
K173236

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary	**K173236**
Date Prepared:	October 02, 2017
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 (K162875)

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 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 device and manufacturing process changes to the Nitinol frame and the Delivery System previously cleared under K162875.

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 device is substantially equivalent in its intended use, principles of operation, design, materials, and sterile package configuration to the cleared Sentry IVC Filter (K162875). There is no change to the fundamental scientific technology or to the intended use.

The primary differences between the predicate and modified device are to the design of the delivery system and overall manufacturing process of the device.

Based on the design verification results, these modifications do not have an adverse impact on the safety and effectiveness of the modified device when compared to the predicate device.

Performance Data

Novate developed a design verification and validation program for the modified 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 studies were undertaken to demonstrate the performance and safety of the modified 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 & dimensional	• Simulated Deployment
• Delivery System integrity	• Accuracy of Deployment
• Filter visual and dimensional	• Packaging Visual Inspection
• Fatigue resistance	• Labeling Visual Inspection
• Filter Corrosion	• Tyvek Pouch Peel
• Migration resistance	• Foil Pouch Peel
• Radial Force	• Bubble Leak Testing
• Ease of device use	• Transportation testing

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

Biocompatibility Evaluations

A biological safety assessment was performed to evaluate the biological risks associated with the modified 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 modified Sentry IVC Filter was also subjected to chemical characterization and a toxicological evaluation performed in accordance with *ISO 10993 Biological Evaluation of Medical Devices - Part 17: Establishment of Allowable Limits for Leachable Substances*. 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).

Conclusions

The modified Sentry IVC Filter is similar in indications, principle of operation, and design to the currently cleared Sentry IVC Filter (K162875) and does not raise different questions of safety and effectiveness. The changes were evaluated by bench testing and biocompatibility studies. Test results demonstrate that the modified device

meets the established specifications and is comparable to the predicate device supporting substantial equivalence. Based on the supportive data provided in this 510(k), it can be concluded that the modified Sentry IVC Filter does not raise new questions of safety or effectiveness compared to the predicate device and is, therefore, substantially equivalent.