January 18, 2024

William Cook Europe ApS
Jennifer Brown
Senior Director, Global Regulatory Science, Vascular Division
Cook Medical
1 Geddes Way
West Lafayette, Indiana 47906

Re: K233680

Trade/Device Name: Celect Platinum® Vena Cava Filter Set for Femoral Vein Approach
Celect Platinum® Vena Cava Filter Set for Jugular Vein Approach
Celect Platinum® Vena Cava Filter Set for Femoral and Jugular Vein Approach
Günther Tulip® Vena Cava Filter Set for Femoral Vein Approach
Günther Tulip® Vena Cava Filter Set for Jugular Vein Approach
Günther Tulip® Vena Cava Filter Set for Femoral and Jugular Vein Approach

Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: November 15, 2023
Received: November 16, 2023

Dear Jennifer Brown:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.01.18 16:18:40 -05'00'

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233680

Device Name

Celect Platinum Vena Cava Filter Set for Femoral Vein Approach (IGTCFS-65-1-FEM-CELECT-PT);
Celect Platinum Vena Cava Filter Set for Jugular Vein Approach (IGTCFS-65-1-JUG-CELECT-PT);
Celect Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach (IGTCFS-65-1-UNI-CELECT-PT);
Günther Tulip Vena Cava Filter Set for Femoral Vein Approach (IGTCFS-65-1-FEM-TULIP);
Günther Tulip Vena Cava Filter Set for Jugular Vein Approach (IGTCFS-65-1-JUG-TULIP);
Günther Tulip Vena Cava Filter Set for Femoral and Jugular Vein Approach (IGTCFS-65-1-UNI-TULIP)

Indications for Use *(Describe)*

The Günther Tulip Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:
• Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
• Failure of anticoagulant therapy in thromboembolic diseases;
• Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and
• Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Günther Tulip Filter implant may be retrieved if clinically indicated; please refer to the “Optional Filter Retrieval” section of the Instructions for Use for more information.

The product is intended for percutaneous placement via a femoral or jugular vein for filtration of inferior vena cava (IVC) blood to prevent PE.

The Celect Platinum Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:
• Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
• Failure of anticoagulant therapy in thromboembolic diseases;
• Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and
• Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Celect Platinum Filter implant may be retrieved if clinically indicated; please refer to the “Optional Filter Retrieval” section of the Instructions for Use for more information.

The product is intended for percutaneous placement via a femoral or jugular vein for filtration of inferior vena cava (IVC) blood to prevent PE.

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.

510(k) Summary

Date Prepared:	November 15, 2023
Submitted By:	William Cook Europe ApS Sandet 6 4632 Bjaeverskov, Denmark
Contact:	Mie Dyrholm
Phone:	+45 56 86 84 92
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Email:	Mie.Dyrholm@CookMedical.com

Device:

Trade Name:	Celect Platinum® Vena Cava Filter Set for Femoral Vein Approach Celect Platinum® Vena Cava Filter Set for Jugular Vein Approach Celect Platinum® Vena Cava Filter Set for Femoral and Jugular Vein Approach Günther Tulip® Vena Cava Filter Set for Femoral Vein Approach Günther Tulip® Vena Cava Filter Set for Jugular Vein Approach Günther Tulip® Vena Cava Filter Set for Femoral and Jugular Vein Approach
Common Name:	Inferior Vena Cava Filter
Classification Name:	Filter, Intravascular, Cardiovascular
Regulation/Product Code:	21 CFR Part 870.3375 / DTK
Classification/Panel:	Class II / Cardiovascular

Predicate Devices:

The Cook Celect Platinum Vena Cava Filter Sets (K211875, cleared 28 July 2021) and the Günther Tulip Vena Cava Filter Sets (K211874, cleared 28 July 2021).

Device Description:

The Celect Platinum Filter Set consists of a filter composed of a paramagnetic cobalt chromium alloy (49 mm long when compressed to a diameter of 30 mm) with platinum markers, preloaded on a femoral filter introducer with a flexible tip; a 7 French coaxial introducer system (compatible with a 0.035 inch wire guide); and a 10 French pre-dilator with hydrophilic coating for vessel access. The introducer dilator has eight sideports and two radiopaque markers 30 mm apart (end-to-end). The Celect Platinum Filter implant is designed to act as a permanent filter or retrievable filter.

The Günther Tulip Filter Set consists of a filter composed of a paramagnetic cobalt chromium alloy (50 mm long when compressed to a diameter of 30 mm), preloaded on a femoral filter introducer; a 7 French coaxial introducer system (compatible with a 0.035 inch wire guide); and a 10 French pre-dilator with hydrophilic coating for vessel access. The introducer dilator has eight sideports and two radiopaque markers 30 mm apart (end-to-end). The Günther Tulip Filter implant is designed to act as a permanent filter or retrievable filter.

Intended Use:

Celect Platinum Filter

The Celect Platinum Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Celect Platinum Filter implant may be retrieved if clinically indicated; please refer to "Optional Filter Retrieval" section of the Instructions for Use for more information.

The product is intended for percutaneous placement via a femoral vein or jugular vein for filtration of inferior vena cava (IVC) blood to prevent PE.

Günther Tulip Filter

The Günther Tulip Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Günther Tulip Filter implant may be retrieved if clinically indicated; please refer to the "Optional Filter Retrieval" section of the Instructions for Use for more information.

The product is intended for percutaneous placement via a femoral vein or jugular vein for filtration of inferior vena cava (IVC) blood to prevent PE.

Comparison to Predicate Device:

The Celect Platinum Vena Cava Filter Sets and the Günther Tulip Vena Cava Filter Sets are identical to the predicate devices in terms of intended use, principles of operation, design, materials of construction, manufacturing processes, sterilization process, and basic technological characteristics. For both devices, the Instructions for Use has been updated to include clinical evidence. For the Celect Platinum Vena Cava Filter Sets, the MRI safety information in the device labeling was also updated. The design requirements and risk assessment are not impacted by the labeling updates and the MRI safety status for the Celect Platinum Vena Cava Filter has not changed. Therefore, the subject Celect Platinum Vena Cava Filter Sets are substantially equivalent to the predicate Cook Celect Platinum Vena Cava Filter Sets (K211875) and the subject Günther Tulip Vena Cava Filter Sets are substantially equivalent to the predicate Günther Tulip Vena Cava Filter Sets (K211874).

Performance Testing:

MRI safety was established in accordance with ASTM F2503-20. Testing included magnetically induced displacement force, magnetically induced torque, and MR image artifact.

Clinical data supporting the updated labeling originated from the Cook IVC Filter Study and the PRESERVE Study, which were Investigational Device Exemption (IDE) studies. Both studies were multi-center, prospective, studies of commercially available inferior vena cava (IVC) filters that were placed in subjects for the prevention of pulmonary embolism (PE). The primary objective of both studies was to evaluate the safety and effectiveness of commercially available IVC filters (retrievable and permanent) in subjects with a clinical need for an IVC filter. The studies included primary safety and primary effectiveness endpoints, as well as secondary endpoints which included evaluation of device safety measures and filter retrieval measures. The two studies demonstrated favorable safety and effectiveness outcomes. The results from the two studies are consistent with previously reported rates for filter complications, including filter embolization, clinically significant perforation, new DVT, caval thrombotic occlusion, and SAEs.

Conclusion:

The subject Celect Platinum Vena Cava Filter Sets and Gunther Tulip Vena Cava Filter Sets are substantially equivalent to the predicate devices (K211875 and K211874). No changes have been made to the IVC filter implant or the delivery systems; only the device labeling has been updated to include clinical evidence and updated MRI safety information.