July 28, 2021

William Cook Europe ApS
Mie Dyrholm,
Director of Regulatory Affairs
Sandet 6, Bjaeverskov, 4632
Denmark

Re: K211874
Trade/Device Name: 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: June 16, 2021
Received: June 17, 2021

Dear Mie Dyrholm:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211874

Device Name
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

Indications for Use *(Describe)*

INTENDED USE

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.

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 **K211874**

Date Prepared: July 27, 2021

Submitted By: William Cook Europe ApS
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4632 Bjaeverskov, Denmark

Contact: Mie Dyrholm
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Email: Mie.Dyrholm@CookMedical.com

Device:

Trade Name:	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 subject Günther Tulip Vena Cava Filter Sets are substantially equivalent to the predicate devices, the Günther Tulip Vena Cava Filter Sets (K172557, cleared 20 November 2017).

Comparison to Predicate Device:

It has been demonstrated that the subject Günther Tulip Vena Cava Filter Sets are substantially equivalent to the predicate Günther Tulip Vena Cava Filter Sets (K172557). The subject devices are identical to the predicate devices in terms of intended use, principles of operation, materials, design, manufacturing, packaging, and sterilization. The device labeling has been updated based on post-market surveillance information and updated documentation in the risk management system.

Device Description:

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 .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.

Indications for Use:

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.

Performance Testing:

No changes to the design, manufacturing, sterilization, or principles of operation have been introduced with the subject devices. Therefore, no performance testing was not warranted, and the testing provided for the predicate submission (K172557) remains supportive.

Conclusion:

The subject Günther Tulip Vena Cava Filter Sets are substantially equivalent to the predicate devices (K172557). No changes have been made to the IVC filter implant or the delivery systems. Only the device labeling has been updated based on post-market surveillance information and updated documentation in the risk management system.