November 20, 2017

William Cook Europe ApS
Henriette S. Christiansen
Director of Regulatory Affairs
Sandet 6, 4632 Bjaeverskov
Denmark

Re: K172584
Trade/Device Name: Günther Tulip Vena Cava Filter Set for Femoral 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: August 25, 2017
Received: August 28, 2017

Dear Henriette S. Christiansen:

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)*
K172584

Device Name
Günther Tulip Vena Cava Filter Set for Femoral Vein Approach
Günther Tulip Vena Cava Filter Set for Femoral and Jugular Vein Approach

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.

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 **K172584**

Date Prepared: 25 August 2017

Submitted By: William Cook Europe ApS
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4632 Bjaeverskov, Denmark

Contact: Henriette Stordal Christiansen
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Device:

Trade Name: Günther Tulip ® Vena Cava Filter Set for Femoral Vein Approach

Günther Tulip ® Vena Cava Filter Set for Femoral and Jugular Vein Approach

Common Name: Inferior Vena Cava Filter

Review Panel: Cardiovascular

Classification Name: Intravascular Filter (21 CFR 870.3375, Product Code DTK)

Classification: Class II

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.

Predicate Device:

The Günther Tulip Vena Cava Filter Sets are substantially equivalent to the predicate devices:

- Günther Tulip Vena Cava Filter Sets cleared under K121057 on 04 May 2012.

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 (K121057). No changes have been made to the Günther Tulip Vena Cava Filter or its delivery systems; the Günther Tulip Vena Cava Filter Sets are identical to the predicate devices in terms of indications for use, principles of operation, design, materials of construction, manufacturing processes, sterilization process, and basic technological characteristics. The purpose of this submission is to update device labeling based on safety and performance information gathered from post-market experience and to align with current international and regulatory standards. In addition, the shelf life of the Günther Tulip Vena Cava Filter has been extended to three years.

Device Description:

The Günther Tulip Vena Cava Filter is an IVC filter intended for use in prevention of recurrent PE. The filter is intended for percutaneous placement via either the jugular vein or femoral vein for filtration of blood within the IVC. The Günther Tulip Vena Cava Filter Set is available in a femoral vein access version and in a universal vein access version consisting of components for both femoral and jugular vein approaches. Each set consists of a filter preloaded on the set for femoral approach, a coaxial introducer system, a hydrophilic coated pre-dilator, and a three-way stopcock. The filter is introduced and placed via a 7 French coaxial introducer system with a Check-Flo® valve. The femoral filter introducer has a flexible tip. The introducer dilator has 8 sideports and two radiopaque markers 30 mm apart. The Günther Tulip Vena Cava Filter is constructed from a cobalt chromium alloy. The end of each leg is hooked outward; this hook design enables securement of the filter to the wall of the inferior vena cava. "Webbed" wires (like tulip petals) between the legs are bent secondary legs which maintain the shape of the filter by pressing outward toward the vein walls. These webs also increase the area into which emboli can be trapped. The filter is approximately 50 mm long along its main axis when compressed to a diameter of 30 mm.

Performance Testing:

No changes to the design, manufacturing, sterilization, or principles of operation have been introduced with the subject devices. A three-year shelf life was supported by nonclinical aging testing, which included packaging testing and performance testing; all test results met the pre-determined acceptance criteria.

Conclusion:

The Günther Tulip Vena Cava Filter Sets are substantially equivalent to the predicate devices. No changes have been made to the filter implant or the delivery systems. The only changes being made are updates to the device labeling and an extension of the device shelf life.