November 6, 2018

Cook Incorporated
Dr. Jennifer Brown, PhD, RAC
Director, Global Regulatory Science, Vascular Division
1 Geddes Way
West Lafayette, Indiana 47906

Re: K181757
Trade/Device Name: Günther Tulip Vena Cava Filter Retrieval Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: October 4, 2018
Received: October 5, 2018

Dear Dr. 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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

For Eleni Whatley
Date: 2018.11.06 10:30:36 -05'00'

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)*
K181757

Device Name
Günther Tulip Vena Cava Filter Retrieval Set

Indications for Use *(Describe)*
The product has been designed for retrieval of implanted Günther Tulip and Cook Celect Vena Cava Filters in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

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.

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510(k) Summary

510(k) Number:	**K181757**
Date Prepared:	29 June 2018
Submitted By:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Jennifer Brown, Ph.D., RAC Director, Global Regulatory Science, Vascular Division
Phone:	(765) 463-7537
Fax:	(765) 497-0641
Email:	JenniferA.Brown@CookMedical.com

Device:

Trade Name:	Günther Tulip® Vena Cava Filter Retrieval Set
Common Name:	Inferior Vena Cava Filter Retrieval Set
Review Panel:	Cardiovascular
Classification Name:	Device, Percutaneous Retrieval (21 CFR 870.5150, Product Code MMX)
Classification:	Class II

Indications for Use:

The product has been designed for retrieval of implanted Günther Tulip and Cook Celect Vena Cava Filters in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

Predicate Device:

The Günther Tulip Vena Cava Filter Retrieval Set is substantially equivalent to the predicate device:

- Günther Tulip Vena Cava Filter Retrieval Set cleared under K073374 on 07 March 2008.

Comparison to Predicate Device:

It has been demonstrated that the subject Günther Tulip Vena Cava Filter Retrieval Set is substantially equivalent to the predicate Günther Tulip Vena Cava Filter Retrieval Set (K073374). Minor changes have been made to the Günther Tulip Vena Cava Filter Retrieval Set; specifically, the dimensions and material of the core wire of the braided platinum wire loop have changed, the outer packaging materials were updated, and the shelf life was extended from 2 years to 3 years. Otherwise, the Günther Tulip Vena Cava Filter Retrieval Set is identical to the predicate device in terms of indications for use, principles of operation, overall design, manufacturing process, sterilization process, and basic technological characteristics. In addition, this submission describes updates to device labeling based on safety and performance information gathered from post-market experience and to align with current international and regulatory standards.

Device Description:

The Günther Tulip Vena Cava Filter Retrieval Set consists of a retrieval loop system with a braided platinum wire loop, a coaxial retrieval sheath system, an entry needle, a wire guide, and a dilator. The outer sheath is provided with a radiopaque band on the distal tip to assist in positioning of the sheath.

The Günther Tulip Vena Cava Filter Retrieval Set is supplied sterile in a peel-open package.

Performance Testing:

The dimensional change, packaging change, and 3-year shelf life extension were supported by the following performance testing which demonstrated that the Günther Tulip Vena Cava Filter

Retrieval Set met applicable design and performance requirements and support a determination of substantial equivalence:

- Performance testing (dimensional, functionality, and tensile testing)
- Distribution testing
- Performance testing (dimensional, functionality, and tensile testing) and package integrity and seal strength testing on 3-year accelerated aged devices
- Simulated use testing on 3-year accelerated aged devices

The material change to the core wire, which is associated with a long history of clinical use in vascular applications and is non-patient contacting, did not require additional performance testing in excess of the performance testing discussed above. No changes to the overall design, manufacturing, sterilization, or principles of operation have been introduced with the subject device; therefore, no additional performance testing was considered necessary.

Summary of Device Labeling Changes:

Device labeling changes were made to reflect added or changed safety information based on post-market surveillance, clinical study data, and information published in regulatory communications and the international test standard on vena cava filters (ISO 25539:2011). The following sections of the Instructions for Use (IFU) were impacted by the labeling changes: Device Description, Warnings, Precautions, Potential Adverse Events, Clinical Studies, step-by-step Instructions for Use, and References.

Conclusion:

The Günther Tulip Vena Cava Filter Retrieval Set is substantially equivalent to the predicate device. The changes being made include a dimensional and material change to the core of the braided platinum loop, an outer material packaging change, an extension of the device shelf life, and updates to device labeling.