May 16, 2023

Cook Incorporated
Daniel Corbin
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47404

Re: K222254
Trade/Device Name: Gunther Tulip Vena Cava Filter Retrieval Set
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: MMX
Dated: April 6, 2023
Received: April 7, 2023

Dear Daniel Corbin:

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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.05.16 10:00:11 -04'00'

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)*
K222254

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.

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COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) SUMMARY

Submitted By:

Daniel Corbin
Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Phone: (812) 325-4172
Fax: (812) 332-0281
Date Prepared: July 26, 2022

Device:

Trade Name:	Günther Tulip Vena Cava Filter Retrieval Set
Common Name:	Inferior Vena Cava Filter Retrieval Set
Classification Name:	Device, Percutaneous Retrieval MMX (21 CFR §870.5150)

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 K181757 on 06 November 2018.

Comparison to Predicate Device:

It has been demonstrated that the Günther Tulip Vena Cava Filter Retrieval Set is substantially equivalent to the predicate device Günther Tulip Vena Cava Filter Retrieval Set (K181757) in terms of intended use, principles of operation, and basic technological characteristics.

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Modifications from the predicate device include: a change to the material used to construct the dilator, and a change from a latex to silicone for the o-ring in the side-arm fitting assembly. The substantially equivalent safety and effectiveness outcomes of the subject device are supported by performance and biocompatibility testing.

Device Description:

The Günther Tulip Vena Cava Filter Retrieval Set is composed 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 intended to retrieve the implanted Günther Tulip and Cook Celect Vena Cava Filters in patients who no longer require a filter.

The Günther Tulip Vena Cava Filter Retrieval Set is a packaged, sterile device intended for single use.

There are no prior submissions for the subject device.

Performance Test Data (non-clinical):

No performance standards have been established under section 514 performance standards, of the Food, Drug and Cosmetic Act for these devices. However, nonclinical tests identified to assess the impact of proposed material and additive changes were performed on the Günther Tulip Vena Cava Filter Retrieval Set to demonstrate that the device meets continues to meet critical design specifications. The Günther Tulip Vena Cava Filter Retrieval Set was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Biocompatibility Testing – Testing was performed in accordance with BS EN ISO 10993-1:2009. The materials and methods used to manufacture the subject device are non-toxic and met the acceptance criteria for their intended use. Testing included: Cytotoxicity, Sensitization, Irritation or intracutaneous reactivity, Acute systemic toxicity, Pyrogenicity, Hemocompatibility
- Dimensional Verification Testing
- Leakage Testing (Time Zero and 3-year Accelerated Aged)
- Tensile Testing

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In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.

Summary of Substantial Equivalence:

Based on the indications for use, design, safety and performance testing the Günther Tulip Vena Cava Filter Retrieval Set meet the requirements for its intended use and are substantially equivalent to the predicate device (K181757).