July 28, 2022

Conmed Corporation
Ms. Kavita Amin, MSRA
Sr Specialist, Regulatory Affairs
ConMed Advanced Endoscopic Technologies
525 French Road
Utica, New York 13502

Re: K221945
Trade/Device Name: Beamer AVEO™ FILTER INTEGRATED ARGON PROBE; Beamer AVEO™ FILTER INTEGRATED ARGON SIDEFIRE PROBE

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 30, 2022
Received: July 5, 2022

Dear Ms. Amin:

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,

For:
Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K221945

Device Name

Beamer AVEO™ Filter Integrated Argon Probes and Beamer AVEO™ Filter Integrated Argon SideFire Probe

Indications for Use *(Describe)*

The Beamer AVEO™ Filter Integrated Argon Probes and Beamer AVEO™ Filter Integrated Argon SideFire Probe are intended to be used for argon enhanced coagulation of tissue.

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

Beamer AVEO™ Filter Integrated Argon Probes

Beamer AVEO™ Filter Integrated Argon SideFire Probe

Submitter Name and Address:

ConMed Corporation
525 French Road
Utica, NY -13502
USA

Contact Person Name and Telephone:

Ms. Kavita Amin, MSRA
Sr Specialist, Regulatory Affairs
ConMed Advanced Endoscopic Technologies

525 French Road
Utica, NY -13502
Telephone: 508-948-2084
Email address: kavitaamin@conmed.com

Date of Summary Prepared:
July 26, 2022

Name of the device:

Trade Name:	Beamer AVEO™ FILTER INTEGRATED ARGON PROBE; Beamer AVEO™ FILTER INTEGRATED ARGON SIDEFIRE PROBE
Common Name:	Beamer AVEO™ Argon Probes
Classification Name:	Class II
Product Code**:**	GEI

Predicate Device:
The Beamer AVEO™ Filter Integrated Argon Probes and Beamer AVEO™ Filter Integrated Argon SideFire Probes are substantially equivalent in function and its intended use as its predicate as listed in **Table 1** below**.**

Table 1: Predicate Device

510(k) Number	Product Code	Trade Name	Manufacturer
K081644	GEI	ConMed Beamer® Argon Probe	ConMed Corporation

Device Description:
The Beamer AVEO™ Argon Probes and Argon SideFire Probe are flexible, single patient use devices which deliver argon for non-contact coagulation when used in conjunction with the Beamer AVEO™ Electrosurgical Generator (ESU) and Argon (ABC) Module. The axial probes are offered in several lengths and diameters to accommodate various endoscope types. The distal end of all the probes has a ceramic tip which provides a thermal insulation barrier for the tubing to prevent heat degradation during coagulation.

Indications for Use:
The Beamer AVEO™ Filter Integrated Argon Probes and Beamer AVEO™ Filter Integrated Argon SideFire Probe are intended to be used for argon enhanced coagulation of tissue.

Substantial Equivalence Comparison:
The modified devices, Beamer AVEO™ Filter Integrated Argon Probes and Beamer AVEO™ Filter Integrated Argon SideFire Probe (Beamer AVEO™ Argon Probes) has the same manufacturing process as the predicate device with the addition of in-line filter prior to packaging and sterilization. The packaging material has been slightly modified to increase robustness of packaging. The modified devices are manufactured with similar material, material specification and processing steps as the predicate device. The addition of in-line filter to the Beamer AVEO Argon Probes and Argon SideFire Probe provide an ease of use to the end-user. The modified devices also include a connector that provides a simple, easy, and unique connection with the Beamer capital equipment. The table below shows the Substantial Equivalence comparison between the predicate and modified device.

Elements	**Predicate Device ConMed Beamer Argon / SideFire Probes**	**Modified Device Beamer AVEO Filter Integrated Argon Probes / SideFire Probe**
510(k)	K081644	K221945
Manufacturer	ConMed Corporation	ConMed Corporation
Regulatory Description	Electrosurgical cutting and coagulation device and accessories.	Same
Product Code	GEI	GEI
Brief Description	The Beamer Argon Probes are flexible, single patient use devices which deliver argon for non-contact coagulation. The probes have two configurations – axial fire probes and a sidefire probe. The axial probes are offered in several length and diameters to accommodate various endoscope types. The distal end of all the probes has a ceramic tip which provides a thermal insulation barrier for the tubing to prevent heat degradation during coagulation.	The Beamer AVEO™ Filter Integrated Argon Probes and Beamer AVEO™ Filter Integrated Argon SideFire Probe are flexible, single patient use devices which deliver argon for non-contact coagulation when used in conjunction with the Beamer AVEO™ System (Beamer AVEO™ Electrosurgical Generator and Beamer AVEO™ Argon Module). The probes are offered in two configuration – axial fire probes and a sidefire probe. The axial probes are offered in various sizes. The distal end of all the probes has a ceramic tip

Elements	Predicate Device ConMed Beamer Argon / SideFire Probes	Modified Device Beamer AVEO Filter Integrated Argon Probes / SideFire Probe
Intended Use/Indications for Use	The Beamer Argon Probes are intended to be used for argon enhanced coagulation of tissue.	The Beamer AVEO™ Argon Probes are intended to be used for argon enhanced coagulation of tissue.
Features		
Outside Diameter	1.8 mm, 2.3 mm, 3.2 mm	Same
Probe Length	180 cm, 230 cm, 320 cm	Same
Overall Length	180 cm, 230 cm, 320 cm	430 cm, 480 cm, 570 cm
Filter	Filter supplied separately with the finished device	In-line Filter
Gas Flow	1.8 mm: 0.3 L/min – 0.6 L/min 2.3 mm: 0.4 L/min – 0.8 L/min 3.2 mm: 0.5 L/min – 1.0 L/min	Same
Connector	Pin plug style connector, which connects to connecting cable	Connector (connect directly to Beamer AVEO™ Argon Module (AVEO-ABC))
Configuration	Sterile, Single-Use	Same
Sterilization Method	Ethylene Oxide	Same

Summary of Technological Characteristics:

The modified devices use the same technological characteristics as the predicate devices except for the following:

- The predicate device uses a reusable extension cable however, the modified devices incorporate an extension tubing as part of a single-use device
- The predicate device is supplied with a separate filter however the modified devices are supplied with an integrated filter for the ease of use
- The predicate device connects to the ESU via a separate Pin Plug Connector however, the modified devices have an integrated single connector that is used to connect the probes with the capital equipment.

Performance Testing:

The modified devices, Beamer AVEO™ Argon Probes, are comprised of similar materials, processes, and packaging as the predicate device (K081644). The sterilization method (EtO) remains unaltered between these devices. The biocompatibility testing conducted on the modified devices confirms the use of materials as safe and effective for its intended purpose.

Performance testing for the modified device includes thermal effects on tissue per FDA Guidance on Electrosurgery and mechanical tests (such as flow rate, insertion and retraction, and tensile strength) were conducted per ConMed Procedures. All test results were acceptable.

Conclusion:

Based on the Performance Testing, Substantial Equivalence Comparison, and Technological Characteristics, the modified devices, Beamer AVEO™ Filter Integrated Argon Probes and

Beamer AVEO™ Filter Integrated Argon SideFire Probe (Beamer AVEO™ Argon Probes), are substantially equivalent to the commercially available marketed device, ConMed Beamer® Argon Probes. The modifications expressed in this 510(k) Premarket Notification do not change the intended use, nor alter the fundamental scientific technology of the device. The modified devices are as safe and as effective as the predicate device.