August 26, 2022

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

Re: K214058
Trade/Device Name: Beamer AVEO Electrosurgical Generator, Beamer AVEO Argon Module

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 29, 2021
Received: July 1, 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)*
K214058

Device Name
Beamer AVEO Electrosurgical Generator and Argon Module

Indications for Use *(Describe)*
The Beamer AVEO™ Electrosurgical Generator System with Accessories is intended to deliver electrosurgical current and Argon gas for the cutting, coagulation and argon beam assisted coagulation of tissue. The Beamer AVEO™ System is used in conjunction with compatible applicators or probes.

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™ Electrosurgical Generator and Argon Module

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: August 23, 2022

Name of the device:

Trade Name:	Beamer AVEO™
Device Name:	Beamer AVEO™ Electrosurgical Generator; Beamer AVEO™ Argon Module
Common Name:	Beamer AVEO™ System, AVEO System
Classification Name:	Class II
Product Code**:**	GEI

Predicate Device:

The information presented in this submission demonstrates the *Beamer AVEO™ Electrosurgical Generator and Argon Module* is substantially equivalent in function to its predicate device, *VIO 300D,* and reference device, *ConMed Beamer System* . The list of predicate and reference devices are provided in **Table 1** below**.**

Table 1: List of Predicate and Reference Devices

	510(k) Number	Product Code	Trade Name	Manufacturer
Predicate Device	K083452	GEI	*VIO 300D*	Erbe
Reference Device	K081678	GEI	*ConMed Beamer System*	KLS Martin

Device Description:

The Beamer AVEO™ Electrosurgical Generator and Argon Module (aka Beamer AVEO System / Beamer AVEO Electrosurgical System) is an electrosurgical generator that is used in surgical procedures and uses High-Frequency (HF) current through an accessory electrode for cutting and coagulation at the operative site. It is also intended to be used for enhanced control of bleeding by the delivery of HF electrosurgical current in combination with Argon gas through a compatible accessory. The Beamer AVEO System can be used for all patient types, conditions where electrosurgery is relevant, on all parts of human body.

The Beamer AVEO System is comprised of an Electrosurgical Generator (AVEO-ESU), Argon Module control (AVEO-ABC), Beamer AVEO cart and accessories (wired foot pedal, pressure reducer). A Graphical User Interface (GUI) and associated footswitches are provided for user interaction. Monopolar instruments, bipolar instruments, Argon probes, and a footswitch are connected to the AVEO system.

Indications for Use:

The Beamer AVEO™ Electrosurgical Generator System with Accessories is intended to deliver electrosurgical current and Argon gas for the cutting, coagulation and argon beam assisted coagulation of tissue. The Beamer AVEO™ System is used in conjunction with compatible applicators or probes.

Summary of Technological Characteristics:

The subject device is similar in design as the predicate and reference devices. The subject device has the same intended use as the predicate and reference devices. The Beamer AVEO System is comprised of an electrosurgical unit and argon unit as the predicate device. All three systems use same technology of high frequency energy for cutting and coagulation of tissue.

Substantial Equivalence:

Table 2 provides the similarities and differences between the predicate and reference devices. The modifications made to the subject device do not raise any risk to safety or effectiveness. Supporting information per this premarket submission confirms that the Beamer AVEO Electrosurgical Generator is safe and effective for its intended use and is substantially equivalent in design, intended use, principals of operation, and technical characteristics to the predicate and reference devices.

Table 2: Substantial Equivalence

Features	**Subject Device: Beamer AVEO System**	**Predicate Device: ERBE VIO 300 D / ERBE APC 2**	**Reference Device: ConMed Beamer System CE600**
510(k)	K214058	K083452 / K024047	K081678
Duty Cycle	Non-continuous 10 seconds/ 30 seconds	Non-continuous 10 seconds/ 30 seconds	Non-continuous 10 seconds/ 30 seconds
Energy Type	High Frequency (HF), Argon	High Frequency (HF), Argon	High Frequency (HF), Argon
Output	Monopolar, Bipolar, Argon	Monopolar, Bipolar, Argon	Monopolar, Bipolar, Argon
Electrical Safety Compliance	IEC 60601-1, Ed. 3.1 IEC 60601-1-2, Ed. 4.0 IEC 60601-2-2, Ed. 6.0	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2

Features	Subject Device: Beamer AVEO System	Predicate Device: ERBE VIO 300 D / ERBE APC 2	Reference Device: ConMed Beamer System CE600
Display	The Beamer AVEO ESU is designed with a 7" touch screen LCD display. The screen displays program, mode, power settings, argon flow rate, argon tank status, neutral electrode status and contact quality (dual-foil electrodes), user programs, and visual indications.	The VIO 300 D is designed with a backlit dual color screen controlled via selection buttons located on either side of the screen. The screen displays program, mode, power settings,	The ConMed Beamer System CE600 is designed with an 8" screen containing push buttons and rotary switch (knob) for navigation. The screen displays program, mode, power settings, argon flow rate, argon tank status, neutral electrode status and contact quality (dual-foil electrodes), user programs, and visual indications.
Foot Pedal Connections	Accommodates the following foot pedal connections: Dual	Accommodates the following foot pedal connections: – Dual Single	Accommodates the following foot pedal connections: – Dual – Single
Purge	The Beamer AVEO System provides a purge function of 3 LPM ± 20% for 4 seconds.	The VIO 300 D with connected APC 2 module provides a 3-second purge with flow rate dependent upon the type of instrument connected to the APC 2.	The Beamer System CE600 provides a purge function of 3 LPM ± 20% for 3 seconds.
Modes	The Display screen has indicators / icons to identify the selected program, power settings for each mode, instrument used and the selected argon gas flow rate.	The Display screen has indicators / icons to identify the selected program, power settings for each mode, and the selected argon gas flow rate.	The Display screen has indicators / icons to identify the selected program, power settings for each mode and the selected argon gas flow rate.
Programmable settings	The Beamer AVEO System is designed to allow users to create, recall, modify, and delete user-defined programs.	The VIO 300 D is designed to allow users to create, recall, modify, and delete user-defined programs.	The Beamer System CE600 is designed to allow users to create, recall, modify, and delete user-defined programs.

Features	Subject Device: Beamer AVEO System	Predicate Device: ERBE VIO 300 D / ERBE APC 2	Reference Device: ConMed Beamer System CE600
Instrument Connections	The Beamer AVEO System accommodates the following instrument connections: – Monopolar (Bovie-type, 3-prong, 4mm) – Bipolar (coaxial, 2-prong) – Argon (ConMed proprietary design)	The ERBE VIO 300 D accommodates the following instrument connections: – Monopolar – Bipolar Argon (via APC Module)	The ConMed Beamer System CE600 accommodates the following instrument connections: – Monopolar (Bovie-type, 3-prong, 4mm) – Bipolar (coaxial, 2-prong) – Argon (Luer connection)

Performance Testing:

Performance testing demonstrates that the Beamer AVEO System is substantially equivalent to the predicate device with regard to its intended use, materials, technology, and performance. Testing demonstrates the devices comply with the applicable sections of AAMI/ANSI ES60601-1, IEC 60601-2-2, and IEC 60601-1-2. Risk management activities in accordance with ISO 14971 demonstrate the risks associated with the use of the Beamer AVEO system are mitigated to an acceptable level. Analyses of these activities conclude the benefits associated with the use of the Beamer AVEO System outweigh the residual risks.

Thermal Effects on Tissue testing was conducted on Beamer AVEO™ Electrosurgical Generator and Argon Module per FDA Guidance, *"Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery".* The test was conducted on three different tissues (Liver, Muscle and Kidney) in triplicate at the minimum, default and maximum settings. The test results and analysis showed that the thermal effects on tissues of the Beamer AVEO™ Electrosurgical Generator and Argon Module are substantially equivalent to the predicate and reference devices. All test results were acceptable.

Conclusion:

The subject device is substantially equivalent to the commercially available marketed device, ConMed Beamer System and Erbe VIO 300D. The modifications expressed in this 510(k) Premarket Notification do not change the intended use, nor alter the fundamental scientific technology of the device, and do not raise any new issues of safety and effectiveness.