March 11, 2022

ConMed Corporation
Lisa Anderson
Senior Lead Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K213354
Trade/Device Name: Unify Multifunction Energy Platform, CleanSeal Vessel Sealers, Unify Bipolar Resection Cables, Unify Wireless FootSwitch, Unify Cart
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 4, 2022
Received: February 9, 2022

Dear Lisa Anderson:

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,

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)*
K213354

Device Name
Unify Multifunction Energy Platform, CleanSeal Vessel Sealers, Unify Bipolar Resection Cables, Unify Wireless FootSwitch, Unify Cart

Indications for Use *(Describe)*

Unify Multifunction Energy Platform and Unify Cart

The CONMED UNIFY is indicated for surgical procedures for the cutting and/or coagulation of tissue when hemostasis is desired.

This generator can be used with compatible resectoscopes for the removal or coagulation of tissue in 0.9% NaCl solution as the irrigation medium.

This generator, when used with compatible vessel sealing devices, is indicated for the ligation and division of tissue bundles, lymphatics, and vessels in open and laparoscopic procedures. Reference instructions for use (IFU) for applicable vessel sealing devices.

The vessel sealing function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

CleanSeal Vessel Sealers

CONMED CleanSeal Vessel Sealers are intended to be used in open and minimally invasive procedures for the ligation and division of tissue bundles, lymphatics, and vessels up to and including 7 mm vessels (arteries and veins). The handpiece is indicated for use in gynecological and general surgical procedures, including urologic and vascular. These procedures include, but are not limited to, hysterectomies, oophorectomies, colectomies, Nissen fundoplication, and adhesiolysis. The CleanSeal Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CleanSeal Vessel Sealer for these procedures.

Unify Bipolar Resection Cables

The CONMED UNIFY Bipolar Resection Cables are used to connect compatible accessories to the CONMED UNIFY ESU. UNIFY Bipolar Resection Cables are used in conjunction with the Bipolar Resection capabilities of the UNIFY ESU for the removal or coagulation of tissue in 0.9% NaCl solution as the irrigation medium. The CONMED UNIFY Bipolar Resection Cables are intended for use with only compatible resectoscopes (refer to Compatibility for details). Maximum rated voltage 750 V.

Unify Wireless FootSwitch

The Wireless Footswitch Kit is intended for use with the CONMED UNIFY™ Advanced Energy Generator for the operation of foot-controlled RF devices.

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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Section 6 - 510(k) Summary of Safety and Effectiveness

ConMed Unify Multifunction Energy Platform with CleanSeal Vessel Sealing Technology

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K213354 as of Jan 12th, 2022.

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

B. Company Contact

Lisa Anderson
Sr. Lead Regulatory Affairs Specialist
M: (941) 713-2035

C. Device Name

Proprietary Name:	Unify Multifunction Energy Platform CleanSeal Vessel Sealers, Unify Bipolar Resection Cables, Unify Wireless FootSwitch, Unify Cart
Common Name:	Electrosurgical Generator
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories 878.4400
Regulation Number:	GEI
Product Code:	II
Regulatory Class:	General and Plastic Surgery
Panel:	

D. Predicate Device

Primary Device Name:	HelixAR ABC System
Company Name:	ConMed Corporation
510(k):	K172671
Secondary Device Name:	Valleylab FT10 Electrosurgical Platform
Company Name:	Covidien LLC
510(k):	K170170
Reference Device Name:	LigaSure Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated
Company Name:	Covidien LLC
510(k):	K170869

E. Device Description

The Unify Multifunction Energy Platform (Unify MEP) is composed of an electrosurgical generator (Unify ESU) with CleanSeal Technology and CleanSeal Vessel Sealing handpieces. The Unify generator is designed with a touchscreen graphic user interface (GUI) display which allows the user to select monopolar and bipolar modes of operation, choose power settings, adjust user settings options, and create, edit, or delete user programs. The Unify ESU is designed for enhanced control of bleeding

and for the electrosurgical destruction of the tissue in multispecialty procedures in the operating room or endoscopy suite. This equipment, in conjunction with connected accessories, is intended to produce high-frequency electrical energy for the controlled destruction of tissue.

The CleanSeal Vessel Sealers are designed to seal vessels up to and including 7mm vessels, tissue bundles, and lymphatics. Unify Bipolar Resection Cables are provided to connect between Unify ESU and compatible resectoscopes.

F. Intended Use / Indications for Use

Unify Multifunction Energy Platform and Unify Cart

The CONMED UNIFY is indicated for surgical procedures for the cutting and/or coagulation of tissue when hemostasis is desired. This generator can be used with compatible resectoscopes for the removal or coagulation of tissue in 0.9% NaCl solution as the irrigation medium. This generator, when used with compatible vessel sealing devices, is indicated for the ligation and division of tissue bundles, lymphatics, and vessels in open and laparoscopic procedures. Reference instructions for use (IFU) for applicable vessel sealing devices.

The vessel sealing function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

CleanSeal Vessel Sealers

CONMED CleanSeal Vessel Sealers are intended to be used in open and minimally invasive procedures for the ligation and division of tissue bundles, lymphatics, and vessels up to and including 7 mm vessels (arteries and veins). The handpiece is indicated for use in gynecological and general surgical procedures, including urologic, and vascular. These procedures include, but are not limited to, hysterectomies, oophorectomies, colectomies, Nissen fundoplication, and adhesiolysis.

The CleanSeal Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the CleanSeal Vessel Sealer for these procedures.

Unify Bipolar Resection Cables

The ConMed UNIFY Bipolar Resection Cables are used to connect compatible accessories to the ConMed UNIFY ESU. UNIFY Bipolar Resection Cables are used in conjunction with the Bipolar Resection capabilities of the UNIFY ESU for the removal or coagulation of tissue in 0.9% NaCl solution as the irrigation medium. The ConMed UNIFY Bipolar Resection Cables are intended for use with only compatible resectoscopes (refer to Compatibility for details). Maximum rated voltage 750 V.

Unify Wireless Footswitch

The Wireless Footswitch Kit is intended for use with the ConMed UNIFY™ Advanced Energy Generator for the operation of foot-controlled RF devices.

G. Technological Characteristics

The Unify MEP is similar to the predicate devices in that the system includes an electrosurgical generator with vessel sealing capabilities used in conjunction with monopolar and bipolar handpieces, footswitches, and an accessory cart. The Unify MEP design includes the non-ABC monopolar and bipolar modes present in the HelixAR Electrosurgical Generator. The design also includes Vessel

Sealing, Soft Coag, and Bipolar Resection modes similar to those in the Valleylab FT10. The output panel of Unify Multifunction Energy Platform provides receptacles for monopolar and bipolar hand- and foot-controlled devices and footswitches. The accessory cart also accommodates the use of additional Unify MEP devices, smoke evacuation units, and accessory storage. The Unify MEP provides Automatic Return Monitoring (ARM) for dual dispersive electrodes as well as visual and audible alerts similar to those used in the predicate designs. The Unify MEP is safe and effective and substantially equivalent to the predicate as demonstrated by non-clinical performance testing.

Features	Unify Multifunction Energy Platform	HelixAR ABC System	ValleyLab FT10/ LigaSure Maryland Jaw Sealer/Divider
Indications for Use	The Unify ESU is indicated for surgical procedures for the cutting and/or coagulation of tissue when hemostasis is desired. The Unify ESU can be used with compatible resectoscopes for the removal or coagulation of tissue in 0.9% NaCl solution as the irrigation medium. The Unify ESU can be used in conjunction with ConMed compatible vessel sealing hand pieces, which are intended to be used in open and laparoscopic procedures for the ligation and division of tissue bundles, lymphatics, and vessels. ConMed CleanSeal Vessel Sealers are intended to be used in open and minimally invasive procedures for the ligation and division of tissue bundles, lymphatics, and vessels up to and including 7 mm vessels (arteries and veins). The handpiece is indicated for use in gynecological and general surgical procedures, including urologic, thoracic, and vascular. These procedures include, but are not limited to, hysterectomies, oophorectomies, colectomies, Nissen fundoplication, and adhesiolysis.	The HelixAR ESU is intended to deliver argon gas, as well as a high-frequency electrical current for the cutting and/or coagulation of tissue.	The FT10 is a high frequency electrosurgical generator intended for use with monopolar and bipolar accessories for cutting and coagulating tissue. When used with compatible sealing devices, it is indicated for sealing vessels up to and including 7 mm, tissue bundles, and lymphatics. The generator can also be used with compatible resectoscopes for endoscopically controlled removal or coagulation of tissue using 0.9% NaCl solution as the irrigation medium. The tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures. The LigaSure Sealer/Divider is a bipolar electrosurgical instrument intended for use in minimally invasive or open surgical procedures where ligation and division of vessels, tissue bundles, and lymphatics is desired. The LigaSure Sealer/ Divider can be used on vessels (arteries and veins) up to and including 7 mm. It is indicated for use in general surgery and such surgical specialties as urologic, vascular, thoracic, and gynecologic. Procedures may include, but are not limited to, Nissen fundoplication, colectomy, cholecystectomy, adhesiolysis, hysterectomy, oophorectomy, etc. The LigaSure system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use the LigaSure system for these procedures.
Target Population	All patient populations	All patient populations	All patient populations
Duty Cycle	15s ON / 30s OFF	15s ON / 30s OFF	10s ON / 30s OFF for any mode for 4 hours

Features	Unify Multifunction Energy Platform	HelixAR ABC System	ValleyLab FT10/ LigaSure Maryland Jaw Sealer/Divider
Energy Type	High Frequency (RF)	High Frequency (RF) with integrated Argon Beam Coagulation	High Frequency (RF) ~434kHz Optional Argon Module
Degree of Protection	Type CF	Type CF	Type CF
Design	– Patient Contact Monitoring System – Continuous microprocessor safety monitoring – LCD with touchscreen – Smart Accessory Connection – Monopolar Remote Power Control	– Patient Contact Monitoring System – Continuous microprocessor safety monitoring – LCD – Monopolar Remote Power Control	– Patient Contact Monitoring System – Continuous microprocessor safety monitoring – LCD with touchscreen – Smart Accessory Connection
Connections	– Monopolar – Bipolar – Bipolar Vessel Sealing – Bipolar Resection – Dispersive Electrode	– Monopolar – Bipolar – ABC – Dispersive Electrode	– Monopolar – Bipolar – Bipolar Vessel Sealing – Bipolar Resection – Dispersive Electrode
Accessories	Cart Corded and Wireless Footswitch Bipolar Resection Cable	Cart Corded and Wireless Footswitch	Cart Corded Footswitch Bipolar Resection Cable

H. Performance Testing

The Unify MEP has been tested according to the applicable requirements listed in FDA guidance "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery" and "Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery". Benchtop and ex-vivo comparison testing, in-vivo simulated use testing, and chronic animal studies support that the ConMed Unify MEP is substantially equivalent to the ConMed HelixAR and Valleylab FT10 Electrosurgical Generators in intended use, technology, and system performance.

Mechanical and electrical verification activities and software validation demonstrate the Unify Multifunction Energy Platform complies with the applicable sections of AAMI/ANSI ES60601-1, IEC 60601-2-2, IEC 60601-1-2, and IEC 62304. Risk management activities in accordance with ISO 14971 demonstrate the risks associated with the use of the Unify Multifunction Energy Platform are mitigated to an acceptable level. Analyses of these activities conclude the benefits associated with the use of the Unify MEP outweigh the residual risks.

I. Biocompatibility Test

The CleanSeal 5mm Vessel Sealer (CleanSeal 5mm VS) used with Unify ESU is in compliance with 2020 FDA Guidance of Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The biological test results support that the CleanSeal 5mm VS met the acceptance criteria for the following biocompatibility test endpoints.

Test Endpoint	**Test Method**
Cytotoxicity	ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5: Tests for In Vitro Cytotoxicity
Intracutaneous Irritation	ISO 10993-10: 2010 Standard, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization.
Sensitization	ISO 10993-10:2010. Biological Evaluation of Medical Devices, Part 10: Tests for

Test Endpoint	Test Method
	Irritation and Skin Sensitization.
Acute Systemic and Material Mediated Pyrogenicity	ISO 10993-11: 2017 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity.

J. Chronic Animal Study

A chronic animal study was conducted according to FDA guidance, “Premarket Notification (510(k)) Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery” Guidance for Industry and Food and Drug Administration Staff, issued on August 15, 2016; and “Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery” Guidance for Industry and Food and Drug Administration Staff, issued on March 9, 2020. The study evaluated the performance of the ConMed Unify ESU with the CleanSeal 5mm Maryland vessel sealing handpiece (Test system) in comparison to the Valleylab FT10 ESU with the LigaSure Maryland with Nanocoating, 37 cm (Predicate system). After 21 days in the porcine model, the treatment of vascular structures (i.e., arteries, veins, and arterio-venous [A/V] bundles) with the ConMed Unify ESU with the CleanSeal 5mm Maryland vessel sealing hand piece was determined to result in the effective sealing of treated vessels.

K. Reprocess

The Unify Reusable Bipolar Resection Cable (BPR Cable) was tested to be compatible with ConMed Unify ESU and Karl Storz or Richard Wolf resectoscopes. The BPR Cable may be cleaned and sterilized up to 50 use cycles. The BPR Cable is designed and manufactured as a reusable device in accordance with FDA Guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” and FDA recognized consensus standard ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices.

L. Substantial Equivalence

The differences between the predicate devices and the proposed device do not raise any new risks of safety or efficacy. Supporting information per this premarket submission, including but not limited to the bench tests, tissue validation, chronical animal study and the benefit-risk analysis, confirms that the Unify MEP is safe and effective for its intended use and is substantially equivalent in design, intended use, principals of operation, and technical characteristics to the ConMed HelixAR and Valleylab FT10 Electrosurgical Generators. The CleanSeal Vessel Sealer, in conjunction with Unify MEP, is also substantially equivalent to the reference device LigaSure Maryland Jaw Sealer/Divider (K170869) used with the predicate ValleyLab FT10.