October 23, 2023

Comed Corporation
Ali Abusaleh
Senior Regulatory Affairs Specialist
525 French Road
Utica, New York 13502

Re: K231732
Trade/Device Name: CleanSeal Advanced Bipolar Vessel Sealer Maryland
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 18, 2023
Received: September 18, 2023

Dear Ali Abusaleh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.10.23 11:57:16 -04'00'

Mark Trumbore, 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

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)*

Device Name
CleanSeal Advanced Bipolar Vessel Sealer Maryland

Indications for Use *(Describe)*
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 6 mm vessels (arteries, veins, pulmonary arteries, pulmonary 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. CleanSeal vessel sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use CleanSeal vessel sealer for these procedures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

CONMED CleanSeal Advanced Bipolar Vessel Sealer Maryland

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

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

B. Company Contact

Ali AbuSaleh
Senior Regulatory Affairs Specialist
(708) 407-4324
Aliabusaleh@conmed.com
Date prepared: 06/13/2023

C. Device Name

Proprietary Name:	CleanSeal Advanced Bipolar Vessel Sealer Maryland
Catalog Numbers:	CS-M5-23, CS-M5-37, CS-M5-44
Common Name:	Bipolar Vessel Sealing Device
Classification Name:	Electrosurgical cutting & coagulation device and accessories
Regulation Number:	878.4400
Product Code:	GEI
Regulatory Class:	II
Panel:	General and Plastic Surgery

D. Predicate Device

Primary Predicate

Device Name:	LigaSure Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated
Company Name:	Covidien LLC
510(k):	K170869

Secondary Predicate

Device Name:	LigaSure Maryland Jaw Thoracic Sealer/Divider, One-step sealing Nano-coated
Company Name:	Covidien LLC
510(k):	K181085

Reference Device

Device Name:	CleanSeal Vessel Sealer 5mm
Company Name:	CONMED
510(k):	K213354

E. Device Description

CleanSeal Advanced Bipolar Vessel Sealer Maryland is designed to be used, with a compatible MEP-1 electrosurgical generator, in open and minimally invasive procedures for the ligation and division of tissue bundles, lymphatics, and vessels up to and including 6 mm arteries and veins. They are sterile, single use bipolar vessel sealing hand pieces featuring double action non-stick coated jaws, three shaft length options, a one-hand controlled handle with latchable lever. The instrument creates a seal by application of radio frequency (RF) electrosurgical energy to vascular structures or tissue bundles interposed between the jaws.

F. Intended Use/ Indications for Use

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 6 mm vessels (arteries, veins, pulmonary arteries, pulmonary 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. CleanSeal vessel sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use CleanSeal vessel sealer for these procedures.

G. Technological Characteristics

CleanSeal Advanced Bipolar Vessel Sealers Maryland (23cm, 37cm and 44cm) connect to the CleanSeal/Bipolar Resection port on MEP-1 via a three-prong ESU plug with a smart chip containing unique parameters specific to the handpiece model. A hand actuated lever allows the user to open or close the instrument jaws during vessel sealing and cutting. An activation button is incorporated into the body of the handle. When connected to MEP-1 and the jaws are shut, the activation button can be pressed to allow the ESU to deliver energy to the CleanSeal Maryland vessel sealer. The cut trigger allows for the transection of tissue, when the jaws are shut, through the deployment of a stainless-steel knife. A rotator knob on the handle allows for 360° rotation of the shaft to position the jaw accurately on the targeted tissue or vessel. The CleanSeal Maryland comes in three shaft lengths (23 cm, 37 cm, and 44 cm). The device is single use.

H. Performance Testing

CleanSeal Advanced Bipolar Vessel Sealers Maryland have 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 CleanSeal Maryland is substantially equivalent to the Ligasure Maryland Jaw nano-coated (primary predicate), Ligasure Maryland Jaw thoracic nano-coated (secondary predicate) and the CleanSeal Vessel Sealer 5mm (reference device) in intended use, technology, and system performance.

Mechanical and electrical verification activities demonstrate the CleanSeal Advanced Bipolar Vessel Sealers Maryland complies with the applicable sections of AAMI/ANSI ES60601-1, IEC 60601-2-2 and 60601-2-18 . Risk management activities in accordance with ISO 14971 demonstrate the risks associated with the use of CleanSeal Maryland is mitigated to an acceptable level. Analyses of these activities conclude the benefits associated with the use of the CleanSeal Maryland outweigh the residual risks.

I. Biocompatibility Test

The CleanSeal Advanced Bipolar Vessel Sealer Maryland 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 Maryland met acceptance criteria for all biocompatibility test endpoints.

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 first test evaluated, in a porcine model, the performance of the CleanSeal Maryland with MEP-1 (Test system) in comparison to the LigaSure Maryland with Nanocoating and Valleylab FT10 ESU, (Primary predicate). After 21 days in the porcine model, the treatment of vascular structures (i.e., arteries, veins, and arterio-venous [A/V] bundles) with the test system was determined to result in the effective sealing of treated vessels. The second test evaluated, in a canine model, the performance of the CleanSeal Maryland with MEP-1 (Test system) in comparison to the LigaSure Maryland thoracic with Nanocoating and Valleylab FT10 ESU, (Secondary predicate). After 21 days in the canine model, the treatment of vascular structures in the thoracic cavity (i.e., Pulmonary arteries, veins, and arterio-venous [A/V] bundles) with the test system was determined to result in the effective sealing of treated vessels.

K. Shelf Life

CleanSeal Advanced Bipolar Vessel Sealer Maryland has a one-year shelf-life based on results of an accelerated aging study. The shelf-life study evaluated the device specifications and package integrity/sterile barrier. The device met all acceptance criteria to support a shelf-life of one year.

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 confirms that the CleanSeal Advanced Bipolar Vessel Sealer Maryland is safe and effective for its intended use and is substantially equivalent in design, intended use, principals of operation, and technical characteristics to the LigaSure Maryland Jaw Sealer/Divider One-step Sealing, Nano-coated, LigaSure Maryland Jaw Thoracic Sealer/Divider, One-step sealing Nano-coated and CleanSeal 5mm Vessel Sealer.

Features	Subject Device: CleanSeal Advanced Bipolar Vessel Sealer Maryland	Reference Device: CleanSeal Vessel Sealer 5mm	Predicate Device: LigaSure Maryland Jaw Open sealer/Divider, One-step sealing Nano-coated	Secondary Predicate: LigaSure Maryland Jaw Thoracic Sealer/Divider, One-step sealing Nano-coated	Comparison/ Discussion
Model Numbers	CS-M5-23, CS-M5-37 and CS-M5-44	CS-M5-23, CS-M5-37 and CS-M5-44	LF1923, LF1937 and LF1944	LF1930T	
510(k)	K231732	K213354	K170869	K181085	
Intended Use/ Indications for Use	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 6 mm vessels (arteries, veins, pulmonary arteries, pulmonary 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. CleanSeal vessel sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use CleanSeal vessel sealer for these procedures.	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. CleanSeal VS has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use CleanSeal VS 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.	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, veins, pulmonary arteries, pulmonary 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.	Similar
Polarity	Bipolar	Bipolar	Bipolar	Bipolar	Identical

Features	Subject Device: CleanSeal Advanced Bipolar Vessel Sealer Maryland	Reference Device: CleanSeal Vessel Sealer 5mm	Predicate Device: LigaSure Maryland Jaw Open sealer/Divider, One-step sealing Nano-coated	Secondary Predicate: LigaSure Maryland Jaw Thoracic Sealer/Divider, One-step sealing Nano-coated	Comparison/ Discussion
Model Numbers	CS-M5-23, CS-M5-37 and CS-M5-44	CS-M5-23, CS-M5-37 and CS-M5-44	LF1923, LF1937 and LF1944	LF1930T	
510(k)	K231732	K213354	K170869	K181085	
Dimensional Design	Jaw size: 5mm Length of shaft: 23cm, 37cm and 44cm Tip Shape: Curve similar to Maryland curve;	Jaw size: 5mm Length of shaft: 23cm, 37cm and 44cm Tip Shape: Curve similar to Maryland curve;	Jaw size: 5mm Length of shaft: 23cm, 37cm and 44cm Tip Shape: Curve similar to Maryland curve;	Jaw size: 5mm Length of shaft: 37 cm Tip Shape: Curve similar to Maryland curve;	Similar
Rated Voltage	350Vpk	350Vpk	288Vpk	288Vpk	Similar
Shelf-life	1 years	1 year	3 years	3 years	Similar
Sterilization Method	Ethylene oxide, SAL of 10^{-6}	Ethylene oxide, SAL of 10^{-6}	Ethylene oxide, SAL of 10^{-6}	Ethylene oxide, SAL of 10^{-6}	Identical
Disposable device	Single patient use device	Single patient use device	Single patient use device	Single patient use device	Identical