DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 29, 2015

CONMED Corporation
Ms. Lisa Anderson
Manager, Regulatory Affairs
525 French Road
Utica, New York 13502

Re: K152860
Trade/Device Name: HelixAR ABC System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 29, 2015
Received: September 30, 2015

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement on last page.*

510(k) Number *(if known)*
K152860

Device Name
HelixAR ABC System

Indications for Use *(Describe)*

The CONMED HelixAR ABC System is intended to deliver argon gas as well as high frequency electrical current for the cutting and/or 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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# 510(k) Summary of Safety and Effectiveness

CONMED HelixAR ABC System

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 K152860 as of December 2, 2015.

## A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502

Establishment Registration: 1320894

## B. Company Contact

Lisa Anderson
Manager, Regulatory Affairs
T: (315) 624-3371
F: (315) 624-3225

## C. Device Name

| | |
|---|---|
| Proprietary Name: | HelixAR |
| Common Name: | Electrosurgical Generator with Argon Beam Coagulation |
| Classification Name: | Electrosurgical, Cutting & Coagulation & Accessories |
| Regulation Number: | 878.4400 |
| Product Code: | GEI |
| Regulatory Class: | II |
| Panel: | General and Plastic Surgery |

## D. Predicate Device

| | |
|---|---|
| Primary Device Name: | System 7500-B (currently System 7550) |
| Company Name: | CONMED Corporation |
| 510(k): | K050161 |

This predicate has not been subject to a design-related recall.

| | |
|---|---|
| Secondary Device Name: | System 5000 |
| Company Name: | CONMED Corporation |
| 510(k): | K020186 |

This predicate has not been subject to a design-related recall.

## E. Device Description

The HelixAR ABC System is composed of an electrosurgical generator with argon beam coagulation (ABC) and a mobile pedestal. The generator is designed with a graphic user interface (GUI) display which allows the user to select monopolar, bipolar, and ABC modes of operation, choose power and argon flow settings, adjust user settings options, and create, edit, or delete user programs. The HelixAR mobile pedestal (cart) houses two D-size argon gas cylinders and provides connection ports for the use of wired footswitches. The mobile pedestal is designed with an argon tank capacity monitor that provides the user with feedback on the argon gas cylinder pressure.

## F. Intended Use / Indications for Use

The ConMed HelixAR ABC System is intended to deliver argon gas as well as high frequency electrical current for the cutting and/or coagulation of tissue.

## G. Technological Characteristics

The HelixAR ABC System is similar to the predicate devices in that the system includes an electrosurgical generator used in conjunction with monopolar and bipolar handpieces and footswitches and an accessory cart. The HelixAR ABC System output panel provides receptacles for monopolar and bipolar hand- and foot-controlled devices. Footswitch receptacles for monopolar, bipolar, and ABC footswitches are provided on the accessory cart which also accommodates the use of a smoke evacuation system. The HelixAR ABC System 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 HelixAR ABC System differs from the predicate devices in that the generator is designed with a GUI display and is compatible with the CONMED Wireless Footswitch Kit. The Wireless Footswitch Kit provides the same functionality as corded footswitches and the convenience of wireless devices. The HelixAR generator design includes the monopolar, bipolar, and ABC modes present in the predicate devices plus the addition of ABC pulse modes. The ABC pulse modes provide the same output characteristics of the other ABC modes with a pulsed application of energy.

## H. Performance Testing

Benchtop and ex-vivo comparison testing as well as in-vivo simulated use testing demonstrate the HelixAR ABC System is substantially equivalent to the ConMed System 7550 and System 5000 with regard to intended use, materials, technology, and performance. Mechanical, electrical, and ex-vivo tissue verification activities and software validation testing demonstrate the devices comply with design requirements and 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 HelixAR ABC System are mitigated to an

acceptable level. Analyses of these activities conclude the benefits associated with the use of the HelixAR ABC System outweigh the residual risks.

## I. 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 ConMed HelixAR ABC System 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 System 7550 and CONMED System 5000.