



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ConMed Corporation
Ms. Dionne Sanders
Manager, Regulatory Affairs
525 French Road
Utica, New York 13502

December 18, 2015

Re: K153499

Trade/Device Name: Arthroscopic Energy System with Accessory Probes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 4, 2015
Received: December 7, 2015

Dear Ms. Sanders:

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,

Joshua C. Nipper -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

Indications for Use

510(k) Number (if known)

K153499

Device Name

Arthroscopic Energy System with Accessory Probes

Indications for Use (Describe)

The Arthroscopic Energy System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic surgical 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.

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 510(k) SUMMARY

I. SUBMITTER

ConMed Corporation
 525 French Road
 Utica, NY 13502

Phone: 727-399-5564
 Fax: 727-399-5264

Contact Person: Dionne Sanders, RAC
 Date Prepared: December 4, 2015

II. DEVICE

Name of Device:	Arthroscopic Energy System
Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Regulatory Class:	Class II, per 21 CFR Part 878.4400
Review Panel:	General and Plastic Surgery Devices
Product Codes:	GEI

III. PREDICATE DEVICE

Device Name:	Arthroscopic Energy System
Company Name:	ConMed Corporation
510(k) #:	K140578

IV. DEVICE DESCRIPTION

The ConMed Arthroscopic Energy System consists of a radiofrequency (RF) generator, probes or electrodes, a dispersive pad (as needed), and wired or wireless foot controls. The probes or electrodes are single-use devices used with the Arthroscopic Energy System for the purpose of wet field arthroscopic and orthopedic soft tissue resection (dissection), ablation (removal) and coagulation (hemostasis).

The generator is compatible with ConMed monopolar and bipolar probes or electrodes. The generator outputs are delivered to the probes or electrode handpieces within the specification ranges currently cleared and marketed by generators that have equivalent indications. The generator has a liquid crystal display (LCD) touch screen user interface. Power levels are assigned numeric values and are adjustable via the



user interface. Control is accomplished via probe or electrode hand-piece controls, wired foot control or wireless foot control.

V. INTENDED USE / INDICATIONS FOR USE

The Arthroscopic Energy System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic surgical procedures.

VI. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table represents a summary of the technological characteristics between the proposed and the predicate device.

	<u>PROPOSED DEVICE</u> ConMed Corporation Arthroscopic Energy System (AES-1)	<u>PREDICATE DEVICE</u> ConMed Corporation Arthroscopic Energy System (AES-1)
Brief Description	A radiofrequency generator that is intended to be used with a selection of bipolar or monopolar probes and electrodes, a dispersive pad (as needed), and wired or wireless foot controls.	A radiofrequency generator that is intended to be used with a selection of bipolar or monopolar probes and electrodes, a dispersive pad (as needed), and wired or wireless foot controls.
Intended Use/ Indications for Use	Indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic surgical procedures.	Indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in arthroscopic and orthopedic surgical procedures.
Functionality	Bipolar and Monopolar radiofrequency	Bipolar and Monopolar radiofrequency
Operating modes	Cut and Coagulation	Cut and Coagulation
Probes	Single-use, disposable bipolar and monopolar probes	Single-use, disposable bipolar and monopolar probes
Footswitch, Extension cable	Yes	N/A



VII. PERFORMANCE DATA

Testing has been completed to demonstrate that the device performs as intended given the modification, and is substantially equivalent to the predicate device.

Completed test data includes the following:

- Footswitch, Extension Cable
 - Verification
 - Validation
- Standards evaluation
 - Electromagnetic compatibility
 - Electrical safety

VIII. CONCLUSION

The Arthroscopic Energy System is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the Arthroscopic Energy System (K140578) and raises no new issues of safety or effectiveness.