CONMED CORPORATION

JUL 2 3 2014

510(k) SUMMARY

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number __K140578__.

Date Prepared: April 10, 2014

A. Submitter

ConMed Corporation
525 French Road
Utica, NY 13502
Establishment Registration Number: 1320894

B. Company Contact

Dionne Sanders, RAC
Regulatory Affairs Specialist
Tel: (727) 399-5564
Fax: (727) 399-5264

C. Device Name

Trade Name:	Arthroscopic Energy System
Common Name:	Electrosurgical Device and Accessories
Classification Names:	Electrosurgical Cutting and Coagulation Device and Accessories
Proposed Class/Device:	Class II
Product Codes:	GEI
Regulation	21 CFR Part 878.4400

D. Predicate/Legally Marketed Devices

Device Name:	ArthroCare® System 12000
Company Name:	ArthroCare Corporation
510(k) #:	K082666

Device Name:	ConMed Sabre Genesis Electrosurgical Generator
Company Name:	ConMed Electrosurgery
510(k) #:	K103665

E. 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.

F. Intended Use / Indications

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.

G. Summary of Technological Characteristics

The following table represents a summary of the technological characteristics of the ConMed Arthroscopic Energy System, ConMed Electrosurgery Sabre Genesis, and the ArthroCare System 12000.

	PROPOSED DEVICE **ConMed Corporation** **Arthroscopic Energy System** **(AES-1)**	**PREDICATE DEVICE** **ArthroCare System 12000** **(Quantum)** **K082666**	**REFERENCE DEVICE** **Sabre Genesis** **K103665**
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 bipolar, high frequency, electrosurgical generator called the Controller that is intended to be used with a family of disposable, bipolar, single use Wands.	An electrosurgical generator with the basic modes of operation being conventional electrosurgical cutting and coagulation.
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 procedures.	Intended for use in open and laparoscopic surgery and in office based surgical procedures.
Functionality	Bipolar and Monopolar radiofrequency	Bipolar radiofrequency	Bipolar and Monopolar radiofrequency
Operating modes	Cut and Coagulation	Cut and Coagulation	Cut and Coagulation
Probes	Single-use, disposable bipolar and monopolar probes	Single-use, disposable bipolar wands	Single-use, disposable bipolar and monopolar probes

Testing was completed to confirm that the Arthroscopic Energy System provides equivalent results in resection, ablation, coagulation and hemostasis in comparison to the predicate device, ArthroCare ® System 12000 (K082666). Testing completed included -

- Probe testing
  - Functional testing
- System testing
  - Suction rate
  - Ablation rate
  - Temperature accuracy
  - Decibel level
  - Short detection testing
  - Comparative testing for dissection, ablation, and hemostatis
- Standards testing
  - Biocompatibility (ISO 10993-1)
  - Packaging (ISO 11607-1)
  - Sterilization (ISO 11135-1)
  - Shelf-life (ISO 10993-7)
  - Electromagnetic compatibility (IEC 60601-1-2; IEC 60601-2-2)
  - Electrical safety (IEC 60601-1)

H. Substantial Equivalence

The Arthroscopic Energy System is substantially equivalent in design, manufacturing materials, intended use, principles of operation, technological characteristics to the ArthroCare® System 12000 (K082666) with the exception of the absence of a monopolar functionality. The subject device and predicate device systems provides bipolar functionality for cutting and coagulation using hand and foot controls which provide the ability to change power settings and measure joint fluid temperature. The Arthroscopic Energy System also provides monopolar functionality and is substantially equivalent in design, principles of operation, technological characteristics, and modes of operation to the ConMed Sabre Genesis (K103665).

I. Conclusion

Based upon the testing and analysis performed, the Arthroscopic Energy is as safe, as effective, and performs as well as the ArthroCare® System 12000 (K082666) for bipolar functionality and the ConMed Sabre Genesis (K103665) for monopolar functionality.

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

July 23, 2014

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

Re: K140578
Trade/Device Name: Arthroscopic Energy™ System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 10, 2014
Received: April 11, 2014

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" (21CFR 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

INDICATIONS FOR USE

510(k) Number (if known): K140578

Device Name: Arthroscopic Energy™ System

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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Joshua C. Nipper -S