510(k) Summary of Safety and Effectiveness

JUL 1 1 2014

ConMed Altrus® Thermal Tissue Fusion 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 _____ as of February 21, 2014.

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
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C. Device Name

Proprietary Name:	Altrus®
Common Name:	Thermal Tissue Fusion System
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number:	878.4400
Product Code:	GEI (79)
Regulatory Class:	II
Panel:	General and Plastic Surgery

D. Predicate Device

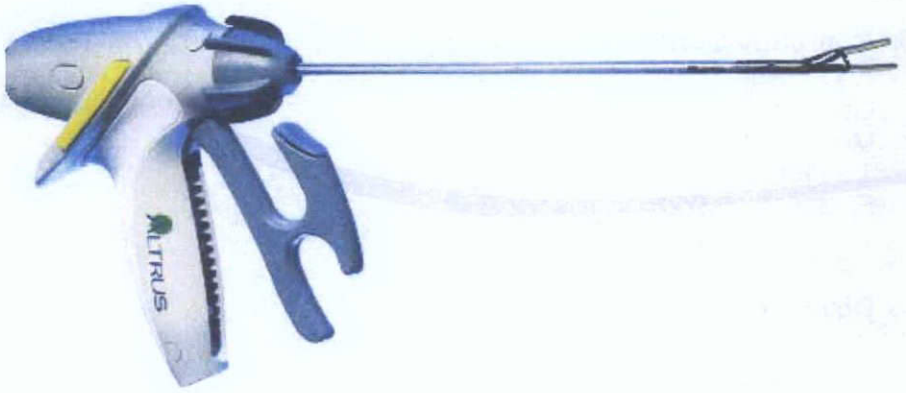
Device Name:	Altrus® Thermal Tissue Fusion System
Company Name:	ConMed Corporation
510(k):	K101534
Device Name:	Ultracision Harmonic Scalpel System
Company Name:	Ethicon Endo-Surgery, Inc.
510(k):	K002906
Device Name:	Ligasure Vessel Sealing System
Company Name:	Valleylab, Inc.
510(k):	K981916

E. Device Description

The modified Altrus Thermal Tissue Fusion System consists of the following devices:

- Altrus Thermal Tissue Fusion Energy Source

- Altrus Thermal Tissue Fusion Handpiece



The modified ConMed Altrus Thermal Tissue Fusion System employs focused thermal energy and pressure to simultaneously seal and/or seal and divide tissue. By applying direct heat instead of electrical, radio frequency or ultrasonic energy, the system can reduce the potential of unintended thermal injury.

The energy source uses as LCD display, a power supply, amplifiers and associated electronic components coupled with several microprocessors and associated software to provide the energy to the accompanying handpiece. The energy source works in harmony with the handpiece in a closed loop communication process. This process allows the handpiece to provide information to the energy source regarding the tissue and adjust the predetermined electrical parameters in response to the effect on the tissue. As energy is delivered to the heaters in the distal portion of the handpiece, these heaters increase in temperature by means of resistive heating. This thermal effect coupled with mechanical pressure on the vessel provides the means for the fusion of the tissue between the jaws to form the ligation (seal). The cutting effect is accomplished in a similar manner, with a different set of parameters controlled by the software.

The modified ConMed Altrus Thermal Tissue Fusion handpiece is a single use device which is provided sterile. The device uses a parallel jaw closure mechanism with one flat jaw and one crowned jaw in which the vessels/tissues are grasped and through which pressure and heat are applied. The handpieces are available in 5mm and 10mm sizes with three shaft lengths for use in laparoscopic and open general surgical and gynecological procedures. Energy is delivered to the heaters by a cable which provides

power to the handpiece as well as allows for communication between the handpiece and the energy source.

The purpose of this submission is to clear the following modifications to the device: (1) change in potting compound from Hysol to EPO-TEK 930-4; (2) change in dimensions and the addition of holes to the spacer component of the handpiece; (3) increase of the maximum number of activations to 450; (4) change in power supply and hardware components of the energy source; (5) modification to the algorithm, seal time and temperature to improve seal performance; (6) slight material changes to accommodate new suppliers; and (7) various changes to improve device manufacturability or cosmetic appearance

F. Intended Use

The Altrus Thermal Tissue Fusion System is comprised of a dedicated energy source and disposable handpiece used to ligate (seal) and divide (cut) blood vessels and tissue bundles that fit into the jaws of the handpiece. The Altrus System utilizes a thermal energy platform to achieve the desired clinical effect.

G. Indications for Use

The ConMed Altrus® Thermal Tissue Fusion System is indicated for open and laparoscopic techniques in general surgical and gynecological procedures for ligating (sealing) and dividing (cutting) of tissue when hemostasis is desired.

H. Non-clinical Performance Testing / Substantial Equivalence

Non-clinical bench and simulated use testing demonstrated the modified Altrus Thermal Tissue Fusion System is substantially equivalent to the identified predicate devices with regard to intended use, materials, technology, and performance. Design verification testing demonstrates the devices comply with design specifications and the applicable sections of AAMI/ANSI ES60601-1:2005, ISO 11607-1:2006, ISO 11135-1:2007, AAMI/ANSI ST67:2011, and ISO 10993-7:2008. Material analysis demonstrates the patient contacting materials of the modified Altrus handpiece comply with the requirements of ISO 10993-1:2009. Performance testing demonstrates the device performance is substantially equivalent to the predicate devices.

I. Conclusions

The differences between the predicate and the modified design do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the modified ConMed Altrus® Thermal Tissue Fusion System is safe and effective for its intended use and is substantially equivalent to the predicate devices.

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 11, 2014

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

Re: K140459
Trade/Device Name: Altrus Thermal Tissue Fusion System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 10, 2014
Received: June 11, 2014

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" (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

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)*
K140459

Device Name
Altrus Thermal Tissue Fusion System

Indications for Use *(Describe)*

The ConMed Altrus Thermal Tissue Fusion System is indicated for open and laparoscopic techniques in general surgical and gynecological procedures for ligating (sealing) and dividing (cutting) of tissue when hemostasis is desired.

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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