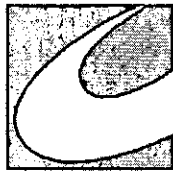


K101534



**CONMED**<sup>TM</sup>  
ELECTROSURGERY

Page 1 of 2

NOV 24 2010

### Summary of Safety and Effectiveness

**Submitted by:** CONMED Electrosurgery Division  
14603 East Fremont Avenue  
Centennial, CO 80112 USA  
Telephone: 303-269-8224  
Facsimile: 866-205-9495

**Contact Person:** Shawn Riedel

**Date Prepared:** March 29, 2010

**Proprietary Name:** CONMED Altrus<sup>®</sup> Thermal Tissue Fusion System

**Classification Name:** Electrosurgical Cutting and Coagulation Device and accessories  
21 CFR 878.4400  
79 GEI

**Predicate Device:** This product is similar in design, composition, and function to the:  
Valleylab LigaSure Vessel Sealing System (K981916) cleared August 28, 1998, as well as the  
UltraCision Harmonic Scalpel System (K002906) cleared December 15, 2000.

#### Device Description:

The CONMED Altrus<sup>®</sup> Thermal Tissue Fusion system consists of the following:

- CONMED Altrus<sup>®</sup> Thermal Tissue Fusion Energy Source
- CONMED Altrus<sup>®</sup> Thermal Tissue Fusion Handpiece.

The CONMED<sup>®</sup> 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 ConMed Altrus products can reduce the potential of unintended thermal injury.

The energy source uses an 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 for 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 simple 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 CONMED Altrus<sup>®</sup> Thermal Tissue Fusion handpiece is a single use device which is provided sterile. The device uses a scissors to 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. It is a multi-functional device capable of vessel sealing, grasping and dissecting during open general surgical procedures. The two jaw sizes allow for applications in a variety of clinical environments for access in confined areas as well as large open areas.

Energy is delivered to the heaters by a cable which provides power to the handpiece as well as allows for communication to and from the handpiece.

**Indications For Use:**

The CONMED ALTRUS<sup>®</sup> 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.

**Technological Characteristics:**

The technological characteristics of the system are similar to the predicate devices. The clinical applications for the sealing and/or separation of tissue are the same. The CONMED Altrus<sup>®</sup> Thermal Tissue Fusion System is different from the predicates in that it utilizes thermal energy versus Radiofrequency energy (Ligasure) or Ultrasonic energy (UltraCision).

Additionally the CONMED Altrus<sup>®</sup> Thermal Tissue Fusion System utilizes thermal energy for cutting versus a mechanical blade found in the predicate (Ligasure).

Both predicate devices are used in general surgical procedures where ligation of vessels is performed.

The CONMED Altrus<sup>®</sup> Thermal Tissue Fusion System complies with all the applicable ISO 60601 Standards as well as being wholly composed of biocompatible materials for all patient or clinician contacting surfaces.

**Performance testing:**

Preclinical laboratory and performance testing were performed to ensure the devices functioned as intended and met design specifications. Sufficient data was obtained to demonstrate the CONMED Altrus<sup>®</sup> Thermal Tissue Fusion System was substantially equivalent to or better than the predicate devices.

**Summary:** The data provide demonstrates the CONMED<sup>®</sup> Altrus Thermal Tissue Fusion system is substantially equivalent to the identified predicate devices in function, construction, intended use, and indications for use.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

ConMed Corporation  
% Intertek Testing Services NA, Inc.  
Ms. Paula Wilkerson, RAC  
2307 East Aurora road, Unit B7  
Twinsburg, Ohio 44087

NOV 24 2010

Re: K101534

Trade/Device Name: CONMED® ALTRUS Thermal Tissue Fusion System  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: November 11, 2010  
Received: November 12, 2010

Dear Ms. Wilkerson:

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

Page 2 - Ms. Paula Wilkerson, RAC

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101534

NOV 24 2000

Device Name: CONMED ALTRUS® Thermal Tissue Fusion System

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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.

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 OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

Page \_\_\_ of \_\_\_

510(k) Number K101534