OCT 2 1 2005

K052104

Summary of Safety and Effectiveness

Submitted by: CONMED Electrosurgery Division
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Contact Person: Pamela L. Vetter

Date Prepared: August 1, 2005

Proprietary Name: UltraClean™ Hand Controlled Suction Coagulator and Foot Controlled Suction Coagulator or other trade names as established

Common Name: Suction Coagulator

Classification Name: Electrode, Flexible Suction Coagulator
(21 CFR 878.4400)
79 GEI

Predicate Device: Suction Coagulator
510(k) # K033003

Device Description: This suction coagulator has applications in general surgical procedures to provide a means of coagulation using electrosurgical current and also provide a means of suction using the vent on the handle. Suction and coagulation can be performed independently or simultaneously. The device consists of a cable for connection to the output of an electrosurgical generator unit, to carry high-frequency (HF) electrosurgical current to the distal end of the handpiece. The handpiece acts as either a hand-switching or foot-switching conduit in delivering the HF energy from the electrosurgical generator unit through the cannula tube to produce the therapeutic affect. Current is activated by the coagulation switching element buttons on the handpiece or by using the footswitch. The devices contain a non-stick (UltraClean™) coating on the cannula tip. The devices will be distributed sterile and non-sterile for single-use applications.

Intended Use of Device: Single-use electrosurgical accessory used to provide coagulation therapeutic energy to tissue and suction to aspirate blood, coagulum and small bits of tissue debris from the surgical site. The coagulation effect is achieved by the passage of high frequency current through the tissue of interest.

Technological Characteristics: The proposed device is equivalent to the identified predicate device with respect to technological characteristics and function. The device has been designed to comply with the applicable sections of ANSI/AAMI American National Standard for Electrosurgical Devices HF-18, the International Electrotechnical Commission Standard for Electrosurgical Devices, IEC 60601-2-2, Sterilization of health care products – Requirements for validation and routine control – Radiation Sterilization, ISO 11137, Medical Devices Risk Management, ISO 14971 and Biocompatibility, ISO 10993.

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BIOCOMPATIBILITY:

The materials and processes used in the construction of the **CONMED UltraClean™ Suction Coagulator** are identical to those of the predicate device with the addition of a silicone-coat (Ultraclean™) on the cannula tip. The original materials have been tested in accordance with accepted biocompatibility test methods and guidance such as ISO 10993 and the General Program Memorandum #G95-1, dated May 1, 1995 and were found to be compatible with the human body. The silicone coating added by ConMed Electrosurgery meets these same requirements and has successfully completed the following biocompatibility testing: Cytotoxicity, Hemolysis, Pyrogen, Intracutaneous Reactivity, Sensitization and Acute Systemic Injection testing (see attached biocompatibility reports).

Table M.1 provides a list of materials used in the construction of the **CONMED UltraClean™ Suction Coagulator** and identifies the devices and applications where those materials are now in use. Please note that this device is not indicated for prolonged direct contact with patient tissue. The distance between the cannula and tissue undergoing coagulation is normally maintained at 1 cm or less and only in temporary contact with tissue undergoing suction.

Table M.1: Material Biocompatibility Summary

Component/Material	Tissue Contact	Preamendment or 510(k) Reference where cleared
Handpiece ABS Plastic	No	Predicate Device: K033003 Suction Coagulator
Cable Wire/Jacket Copper wire/PVC jacket	No	Predicate Device: K033003 Suction Coagulator
Cable Contacts Brass	No	Predicate Device: K033003 Suction Coagulator
Cannula Aluminum	Yes	Predicate Device: K033003 Suction Coagulator
Cannula Insulator Polyolefin	Yes	Predicate Device: K033003 Suction Coagulator
Tip Silicone (Ultraclean™)	Yes	Biocompatibility test reports attached

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 1 2005

Pamela Vetter
Manager of Regulatory Affairs
ConMed Electrosurgery
14603 East Fremont Avenue
Centennial, Colorado 80112

Re: K052104/S1
Trade/Device Name: Ultraclean Suction Coagulator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 27, 2005
Received: September 28, 2005

Dear Ms. Vetter:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Barbara Price MD
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050104

Device Name: CONMED UltraClean™ Suction Coagulator

Indications for Use:

Single-use electrosurgical accessory used to provide coagulation therapeutic energy to tissue and suction to aspirate blood, coagulum and small bits of tissue debris from the surgical site. The coagulation effect is achieved by the passage of high frequency current through the tissue of interest.

Prescription Use X OR Over-The-Counter ____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Burns for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K05 2104