Summary of Safety and Effectiveness

K081634

Submitted by:	CONMED Electrosurgery Division 14603 East Fremont Avenue Centennial, CO 80112 USA Telephone: 303-269-8224 Facsimile: 303-699-9854
Contact Person:	Shawn Riedel
Date Prepared:	25 April 2008
Proprietary Name:	CONMED® GoldVac™ Integrated Smoke Evacuation Pencil
Common Name:	Electrosurgical pencil accessory for surgical smoke evacuation
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 ConMed Smoke Evacuation Attachment of 510(k) Notification K982309 cleared August 5, 1998, as well as the Electrosurgical Pencil K791137 cleared July 24, 1979.

JUN 25 2008

Device Description: The CONMED® GoldVac™ Integrated Smoke Evacuation Pencils a sterile, single use integrated electrosurgical pencil and smoke evacuation handpiece. The device is intended for general electrosurgical applications and when used in conjunction withan effective smoke evacuation system, for removing smoke generated by electrosurgery.

The integration of the pencil and the smoke attachment allows a single device to be used. The need for smoke removal is demonstrated in numerous studies documenting the effects of surgical smoke. It has been well documented the smoke produced from electrosurgery contains carbonized tissue, airborne particles, and various chemicals and gases. The Occupational Health And Safety Administration has issued recommendations that surgical smoke be removed and properly filtered by a smoke evacuation system as close to the surgical site as possible. The traditional surgical mask has been determined to be not adequate for personal protection. The device is constructed of thermoplastics well known throughout the industry in the manufacture of medical devices. The device consists of electrosurgical pencil with an integrated pathway for smoke removal. This pathway forms an airway from the tip to the rear of the pencil. The pencil is connected to tubing which will be attached to the rear of a variety of smoke evacuation systems. The smoke is then filtered by smoke evacuation system preventing personnel exposure to this surgical smoke. The device will be packaged singly for sterile distribution.

The CONMED® GoldVac™ Integrated Smoke Evacuation Pencil incorporates an extendable "smoke tube" which is housed within the electrosurgical pencil. The pencil is connected to the 10 feet of tubing which connects the pencil to the smoke evacuation system.

Technological Characteristics: The CONMED® GoldVac™ Integrated Smoke Evacuation Pencils are simply an integration of the electrosurgical pencil and the smoke evacuation attachment. The only visible difference is this integration and the addition of a "smoke tube" which can be positioned near the tip of the electrode for maximum smoke removal or farther back for maximum accessibility and visibility.

The tubing houses the cord set to eliminate clutter at the surgical site and swivels to allow for a maximum range of motion.

The technological characteristics of the electrosurgical pencil remain the same. As with the predicate device, CUT, COAG, and smoke evacuations are contained in one device, limiting the need for several devices present at the surgical site that perform these functions independently of each other.

The proposed device is equivalent to the identified predicate devices 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, 60601-2-2, Risk Management ISO 14971 and Biocompatibility ISO 10993.

- There are no changes to the generator and therefore no changes to the accompanying software.
- The operator controls the use of the device;
- The generator provides alarms for conditions that could pose a risk to the patient;
- The operator sets the appropriate mode and output settings for the device.

Performance testing: Bench testing on the subject device has shown the device to perform as intended with the same or similar results as a predicate device. No particular requirements peculiar to this smoke performance exist in the standards but tests conducted with the device have shown no effect or changes to the function of the electrosurgical pencil. The removal of smoke was similar to that of the two independent devices. The nozzle or intake portion of the device has been designed so as to not impede the operation of the electrosurgical function of the pencil and provides for intake of the surgical smoke for filtering

Intended Use: The GoldVac pencils, when used with an effective smoke evacuation system, removes smoke plume from the surgical site. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

Summary: The CONMED® GoldVac™ Integrated Smoke Evacuation Pencil is equivalent to the identified predicate devices. In addition, it is equivalent in its intended use and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2008

ConMed Corporation
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K081634
Trade/Device Name: CONMED® GoldVac™ Integrated Smoke Evacuation Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 3, 2008
Received: June 11, 2008

Dear Mr. Lehtonen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K081634

Device Name: CONMED® GoldVac™ Integrated Smoke Evacuation Pencil

Indications for Use:

The GoldVac pencils, when used with an effective smoke evacuation system, removes smoke plume from the surgical site. The pencil enables the operator to remotely conduct an electrosurgical current from the output connector of an electrosurgical unit to the operative site for the desired surgical effect.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K081634

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