K103665

FEB 16 2011

510k Summary of Safety and Effectiveness

CONMED® Sabre Genesis™ Electrosurgical Unit
CONMED® HyfreSurg OP™ Electrosurgical Unit

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92. ConMed Electrosurgery is hereby submitting the 510(s) Summary of Safety and Effectiveness for the 510(k) Number _____ as of December 1, 2010.

A. Submitter

ConMed Electrosurgery
14603 E. Fremont Ave.
Centennial, Colorado 80112

B. Company Contact

Shawn Riedel
Vice President, Quality Assurance and Regulatory Affairs
14603 E. Fremont Ave.
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C. Device Name

Trade Name:	CONMED® Sabre Genesis™ Electrosurgical Unit CONMED® HyfreSurg OP™ Electrosurgical Unit
Common Name:	Electrosurgical unit and accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and accessories
Regulation Number:	21 CFR 878.4400 Class II 79 GEI
Panel:	General and Plastic Surgery

D. Predicate Device Name

CONMED® System 2450™ Electrosurgical Unit
ConMed Electrosurgery
510(k) K052009

CONMED® System 5000™ Electrosurgical Unit
ConMed Electrosurgery
510(k) K020186

E. Device Description

The CONMED® Sabre Genesis™ and CONMED® HyfreSurg™OP Electrosurgical Generators are electrosurgical generators with the basic modes of operation being conventional electrosurgical cutting and coagulation. The devices consist of a single electrosurgical generator unit for each model to supply high frequency (HF) electrosurgical current to accessory hand pieces to produce the clinical effect. When cutting, the subject device provides the energy to the edge of the active electrode which is drawn across the tissue while electrosurgical energy is being applied. When coagulating, the subject device provides the energy to the active electrode which may be held in contact with the tissue for desiccation or separated from the tissue by distance for fulguration to achieve the desired result.

The subject devices (Sabre Genesis and HyfreSurg OP) are of the same construction in components and assembly. The difference is the HyfreSurg OP does not have the Pulse Cut functionality and the control panel is altered accordingly.

Use of these products for unintended applications could lead to an unsafe condition.

The device utilizes previously cleared/marketed and required accessories.

F. Intended Use

The CONMED® Sabre Genesis™ and CONMED® HyfreSurg OP™ Electrosurgical Generators are intended for use in open and laparoscopic surgery and in office based surgical procedures.

G. Indications for use

General-purpose electrosurgical generator used in conjunction with an electrosurgical accessory hand piece for delivery of RF (radio frequency) electrosurgical content through an accessory electrode for the cutting and coagulation at the operative site.

H. Technological Characteristics

The technological characteristics of the proposed device are identical to the predicate devices. Any differences represent limitations of previously cleared technology. The device has been designed to comply with numerous applicable standards.

I. Safety Information

Questions of safety and effectiveness are the same for this device as they are for the predicated devices and other electrosurgical generators on the market. There are no new technologies incorporated into the device. The device provides alarms for conditions that could pose a risk to the patient. The operator sets the appropriate mode and output settings for the device.

J. Biocompatibility

The subject devices do not have direct patient contact.

K. Performance Testing

Where applicable, specific testing performed was in conformance with the requirements of the following standards:

- IEC 60601-1:1998, Medical electrical equipment – 2nd Ed. plus amendments 1 and 2 - also representing UL60601-1, EN60601-1, CSA C22.2 No. 60601-1 except for national deviations.
- IEC 60601-1-1: 2000, Medical Electrical Equipment – Part 1-1 General Requirements for Safety – Collateral Standard: Safety Requirements for Medical Electrical Systems.
- IEC 60601-1-2: 2005, Medical Electrical Equipment – Part 1-2 General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
- IEC 60601-1-4: 2000, Medical Electrical Equipment – Part 1-4 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems.
- IEC60601-1-6: 2004, Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability.
- IEC60601-1-8: 2005, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- IEC 60601-2-2: 2006, Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment.

L. Subject vs. Predicate Device

The subject device(s) are of the same inherent technology and construction as the predicate devices. The chasis and the bezel for the devices are essentially the same dimensionally and are fabricated from the same materials. The subject devices have a universal power supply not found in the predicate devices.

Performance characteristics of the subject devices are equivalent to the subject devices and have been verified to meet the requirements above as well as performance requirements defined in design inputs. Design verification and validation activities demonstrated the subject devices to be equivalent where applicable to the predicate devices.

Specific differences between the subject and predicate devices are found in the substantial equivalence table.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ConMed Electrosurgery
% Mr. Shawn Riedel
Vice President of Quality Assurance and Regulatory Affairs
14603 East Fremont Avenue
Centennial, Colorado 80112

FEB 16 2011

Re: K103665
Trade Name: CONMED® Sabre Genesis™ Electrosurgical Generator
CONMED® HyfreSurg™ OP Electrosurgical Genertaor
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 1, 2010
Received: December 16, 2010

Dear Mr. Riedel:

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 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" (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 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,

for

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): _____

Device Name: CONMED® Sabre Genesis™ Electrosurgical Generator
CONMED® HyfreSurg™OP Electrosurgical Generator

Indications for Use:

General-purpose electrosurgical generator used in conjunction with an electrosurgical accessory handpiece for delivery of RF (radio frequency) electrosurgical content through an accessory electrode for the cutting and coagulation at the operative site.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103665