SEP 2 8 2005

K052009

Summary of Safety and Effectiveness

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

Date Prepared: July 21, 2005

Proprietary Name: CONMED System 2450 ESU

Common Name: Electrosurgical Unit and Accessories

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

Predicate Device: CONMED Sabre 2400 ESU, K905654, cleared March 18, 1991
CONMED System 5000 ESU, K020186, cleared April 12, 2002
Valleylab Force FX™ ESU, K944602, cleared June 5, 1995

Device Description: The System 2450 is an electrosurgical generator with the basic modes of operation being conventional electrosurgical cutting and coagulation. When cutting, the edge of the electrode is drawn across the tissue while electrosurgical energy is being applied. When coagulating, the accessory electrode 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 device consists of an electrosurgical generator unit to supply high frequency (HF) electrosurgical current to accessory handpieces to produce the therapeutic effect. The device utilizes previously cleared/marketed and required accessories.

Intended Use of Device: The System 2450 is a general-purpose electrosurgical generator used in conjunction with an electrosurgical accessory handpiece for delivery of RF (radio frequency) electrosurgical current through an accessory electrode for cutting and coagulation at the operative site.

Technological Characteristics: 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, IEC 60601-1, 60601-1-1, 60601-1-2, 60601-1-4, 60601-1-6, 60601-1-8, 60601-2-2, Underwriter's Laboratory UL60601-1, Risk Management ISO 14971 and Biocompatibility ISO 10993.

Software for the System 2450 ESU will be validated in accordance with internal ConMed Electrosurgery procedures including the FDA guidance "General Principles of Software Validation". The level of concern for the ConMed System 2450 is "Moderate" as defined in the FDA guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. This is based on the following considerations:

- The System 2450 software will be validated and verified according to documented procedures, which include, but are not limited to System Level Hazard Analysis, peer review of software design and software module testing. All validation and verification activities will be completed prior to commercial distribution;
- Output characteristics are equivalent to the values for other previously cleared electrosurgical generators;
- The operator controls the use of 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2005

Ms. Pamela Vetter
Manager of Regulatory Affairs
CONMED Electrosurgery
14603 East Fremont Avenue
Centennial, Colorado 80112

Re: K052009
Trade/Device Name: CONMED SYSTEM 2450 ESU
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 21, 2005
Received: July 25, 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/dsma/dsmamain.html

Sincerely yours,

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): K052009

Device Name: CONMED SYSTEM 2450 ESU

Indications for Use:

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

Prescription Use ✓ 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)

Mark N Milhous

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

510(k) Number K052009