Summary of Safety and Effectiveness

Submitted by:	CONMED Electrosurgery Division 14603 East Fremont Avenue Centennial, CO 80112 USA Telephone: 303-699-7600 Facsimile: 303-699-9854
Contact Person:	Pamela L. Vetter
Date Prepared:	July 8, 2004
Proprietary Name:	ValuPen™, Profile® and other trade names as established
Common Name:	Disposable Electrosurgical Pencil
Classification Name:	Electrosurgical Cutting and Coagulation Device and accessories (21 CFR 878.4400) 79 GEI
Predicate Device:	Disposable Electrosurgical Pencils 510(k) # K936304

SEP 28 2004

Device Description: This pencil has applications in general surgical procedures to provide a means of cutting and coagulation using electrosurgical current. The device consists of a cable for connection to the output of an electrosurgical generator unit, to carry high-frequency (HF) electrosurgical current to an electrode tip at the distal end of the handpiece. The handpiece is provided with various electrode types and cable lengths and acts as a hand-switching conduit in delivering the HF energy from the electrosurgical generator unit through an electrode to produce the therapeutic affect. Current is activated by the cut/coagulation switching element buttons on the handpiece. The devices will be distributed sterile for single-use applications.

Intended Use of Device: Single-use hand-switching electrosurgical accessory handpiece used in conjunction with an electrosurgical generator for delivery of RF electrosurgical current through an electrode for cutting and coagulation at the operative site.

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 and Biocompatibility, ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2004

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

Re: K041868
Trade/Device Name: Disposable Electrosurgical Pencil
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 8, 2004
Received: July 9, 2004

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 (301) 594-4659. 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,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K041868

Device Name: Disposable Electrosurgical Pencil

Indications for Use:

Single-use hand-switching electrosurgical accessory handpiece used in conjunction with an electrosurgical generator for delivery of RF electrosurgical current through an electrode for cutting and coagulation at the operative site.

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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K041868