

NOV 16 1999

K993647

Safety and Effectiveness Summary

Common / Usual Names: Disposable Hand and Foot-Switching Pencils with Holster, Non-Coated Electrode and Tip Cleaner

Disposable Hand and Foot-Switching Pencils with Holster and Coated Electrode

Classification:

Class II

Materials:

All materials used in the manufacture of the Unimed Pencil combinations are non-toxic and been used in previously legally marketed devices.

Description:

The Electrosurgical Pencils are for the cutting and coagulation of soft tissue and have a 3-pin connector attached to a 10 foot conductive cable and are designed for use with standard electrosurgical generators (ESU). The connector or plug fits into the monopolar side of a standard electrosurgical unit. The handpieces are made of plastic with two buttons or a rocker switch toward the distal part of the pencil in the case of the hand-controlled pencils, while the foot-controlled pencil that is connected to the generator by means of an adapter activated by a monopolar footswitch. One button or switch is to control the CUT mode of the ESU while the other controls the COAG mode.

The Holster is intended to store the pencil while it is not actively in use that attaches to a surgical drape and avoids accidental activation when not in use

The Tip Cleaner is intended to be used for eschar removal that tends to build up on an uncoated electrode by gently scraping it along the aggressive surface. The Tip Cleaner attaches to a surgical drape by an adhesive backing.

The Coated Electrode is an electrode use to cut and coagulate soft tissue coated with a material intended to reduce the build up of eschar usually eliminating the need for a Tip Cleaner.

Pencils packaged with Coated Electrodes will not have a Tip Cleaner.



NOV 16 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lee Alexander
President and Chief Executive Officer
Unimed Surgical Products, Inc.
10401 Belcher Road
Largo, Florida 33777

Re: K993647
Trade Name: Disposable Hand and Foot-Switching Pencils
Regulatory Class: II
Product Code: GEI
Dated: October 28, 1999
Received: October 29, 1999

Dear Mr. Alexander:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

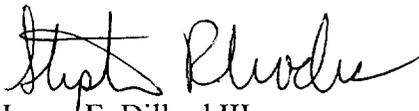
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for 

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

o Intended Use

K993647

Intended / Indication for Use. The Electrosurgical Pencils and Electrodes are used for the cutting and coagulation of soft tissue. The Intended Use of the modified device, as described in its labeling, has not changed as a result of the modifications and do not alter the scientific technology of the device.

Steph Rivels
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993647

Over-the-Counter Use _____

Prescription Use X
(Per 21 CFR 801.109)