DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1996

Mr. Ronald R. Froemming
Chief Operating Officer
Unimed Surgical Products, Inc.
10401 Belcher Road
Largo, Florida 34647

Re: K962935
Unimed Coated Needle Electrode, Unimed Coated Blade Electrode, Unimed Coated Ball Electrode
Regulatory Class: II
Product Code: GEI
Dated: July 26, 1996
Received: July 29, 1996

Dear Mr. Froemming:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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 at (301) 443-6597.

Sincerely yours,

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

Enclosure

510(k) Number (if known) K962935

Device Name: Electrosurgical Electrode

Indications For Use:

The ***unimed*** Coated Electrodes are indicated for use in the cutting and coagulation of soft tissue.

(PLEASE DO NO WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K962935

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

SAFETY AND EFFECTIVENESS SUMMARY

COMMON/USUAL NAME: Electrosurgical Electrode

PROPRIETARY NAME: ***unimed*** Coated Needle Electrode, ***unimed*** Coated Blade Electrode, and ***unimed*** Coated Ball Electrode

CLASSIFICATION: CLASS II

MATERIALS: All materials used to manufacture the Coated Electrodes are non-toxic and have been used in previously marketed devices.

DESCRIPTION:

The Coated Electrodes are coated with Emralon 333 or Teflon 420-104. Both are dry lubricants which provide a low coefficient of friction and reduce eschar build-up during surgery and the need for higher power settings. Without eschar build-up that takes place with a standard stainless steel tip less scraping and inconvenience takes place resulting in greater OR efficiency.

Emralon and Teflon are non-toxic, corrosion resistant, and therefore safe for the patient and the OR staff.

The Coated Electrosurgical Electrodes are available in a variety of tip configurations and lengths. The tip configurations include blades, needles, and balls. The blades and needles are also available with the tips only partially exposed.

These devices are designed to cut and coagulate soft tissue during surgical procedures. The entire line of electrodes will fit all button, rocker, and foot-controlled pencils. The electrodes are available sterile, single use only.

SUBSTANTIAL EQUIVALENCE: ***unimed's*** electrodes are currently sold in the USA under numerous proprietary names by other medical device companies. ***unimed*** Surgical Products, Inc. is presently a component supplier of these parts. ***unimed*** Surgical Products, Inc. now wants to market these devices under its own trade name, as well as maintain the component supplier status.