



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 5 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Union Medical Engineering Company, Limited  
c/o Ms. Annie Velez  
SHE Medical, Incorporated  
President & Director of Regulatory Affairs  
8930 South West 68<sup>th</sup> Court #H3  
Miami, Florida 33156

Re: K981430  
Trade Name: UM-D30 Coagulator  
Regulatory Class: II  
Product Code: GEI  
Dated: April 15, 1998  
Received: April 20, 1998

Dear Ms. Velez:

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.

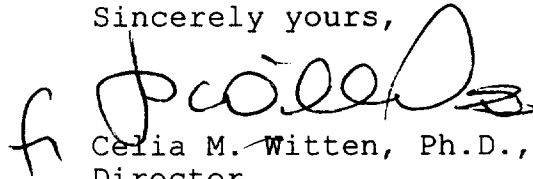
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

A handwritten signature in dark ink, appearing to read 'C. Witten', with a large, stylized initial 'C' and a long, sweeping horizontal stroke extending to the right.

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

## INDICATION FOR USE STATEMENT

510(k) Number: K981430

Device Name: Coagulator

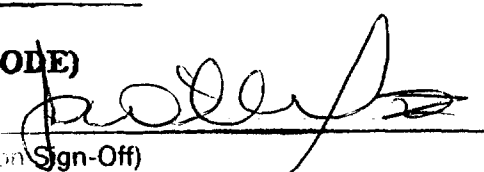
Device Model: UM-D30

### Indications for Use:

The UM-D30 Coagulator is used in small surgical procedures in dermatology, plastic surgery and general surgery in order to only coagulate (burn) an open wound or skin lesions. This device does not cut the skin, it only closes open wounds or lesions by coagulating (burning) the skin in any of the small surgical procedures mentioned above.

Federal Law restricts the use of this device by or on the order of a qualified physician only.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K981430

Prescription Use ☒ OR Over the Counter Use ☐

(Per 21 CFR 801.109)