DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Union Medical Engineering Co., Ltd.
c/o Ms. Annie Velez
Director
She Medical Systems
1200 N.W. 78th Avenue
Suite 110
Miami, Florida 33126

Re: K982860
Trade Name: UM-L20; UM-L30 Carbon Dioxide Laser and Accessories
Regulatory Class: II
Product Code: GEX
Dated: May 3, 1999
Received: June 21, 1999

Dear Ms. Velez:

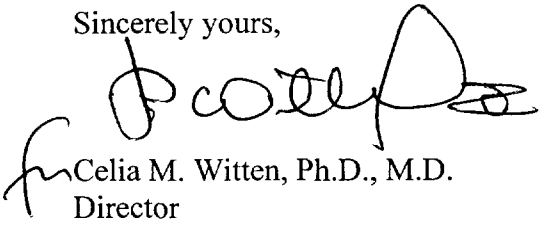
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



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: K982860

Device Name: CO2 Lasers

Device Model: UM-L20/UM-L30

Indications for Use:

The UM-L20/UML30 CO2 Laser Units are used in the following applications in order to treat the below mentioned conditions:

ENT	*Plastic & Reconstruction*	*Dermatology*	*Podiatry*
Adenoidectomy	Xanthoma	Xanthoma	Tumors
Oral Tumors	Nasal Polyps	Telangiectasia	Hemostasis
Rhinophyma	Condyloma	Rhinophyma	Keloids
Tumors	Rhinitis	Condyloma	Verruce
Nasal Polyps	Tumors	Tumors	Skin Tags
Hemostasis	Telangiectasia	Hemostasis	Nevi
Rhinitis	Hemostasis	Keloids	Skin Incisions
Keratosis	Rhinophyma	Verruce	
Tonsillectomy	Keloids	Skin Tags	
Verruce Nevi	Keratosis	Nevi	
Skin Tags	Skin Tags	Dark Spots	
	Skin Incisions	Corn	
	Verruce	Syringoma	
	Nevi		

(Division Sign-Off)
Division of General Restorative Devices K982860
510(k) Number

Prescription Use X
(Per 21 CFR 801.109)

Indication for Use, Page 2
K982860, UM-L20 & UM-L30 CO2 Lasers

Dentalogy	*General Practice*	*Gynecology*	*Proctology*
Gingival Incision & Excision	Rhinitis	Condyloma	Tumors
Tissue Retraction for Impression	Xanthoma	Conization	Hemostasis
Frenectomy & Frenotomy	Condyloma	Tumors	Hemorrhoids
Aphthous Ulcers	Tumors	Hemostasis	Keloids
Excisional & Incisional Biopsies	Keloids	Keloids	Keratosis
Draining of Abscesses	Keratosis	Keratosis	Verrucae
Hemostatic Assistance	Verrucae	Verrucae	Skin Tags
Implant Exposure	Skin Tags	Skin Tags	Nevi
Soft Tissue	Nevi	Nevi	Skin Incisions
Crown Lengthning			
Operculectomy			

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR Over the Counter Use** _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982860