



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 12 1999

Marilyn M. Chow, Ph.D.  
Regulatory Consultant  
MedArt Corporation  
11772 Sorrento Valley Road  
Suite 240  
San Diego, California 92121

Re: K991297  
Trade Name: Uni-Laser 450P CO2 Laser System & Accesories  
Regulatory Class: II  
Product Code: GEX  
Dated: June 23, 1999  
Received: June 24, 1999

Dear Dr. Chow:

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.

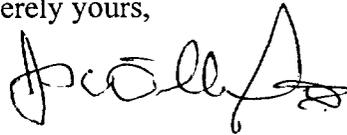
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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

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) 594-4659. 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

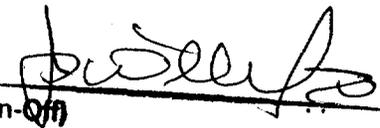


**Gynecology** Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies) and vulvar and vaginal intraepithelial neoplasia.

**Neurosurgery** Laser incision, excision, ablation and/or vaporization of soft tissue in neurology for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X   OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801.109)

  
\_\_\_\_\_  
Sign-Off  
Division of General Restorative Devices  
STOCK Number   K991297