



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 11 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jan K. Enemaerke
President
MedArt Corporation
11772 Sorrento Valley Road, Suite 240
San Diego, California 92121

Re: K993815
Trade Name: MedArt Corporation Uni-Laser™ 430
Regulatory Class: II
Product Code: GEX
Dated: February 7, 2000
Received: February 11, 2000

Dear Mr. Enemaerke:

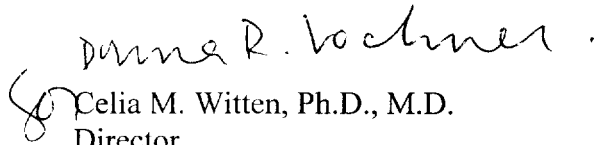
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K993815Device Name: MedArt Corporation Uni-Laser™ 430

Indications for Use Statement:

The Uni-Laser™ 430 is intended for use in hair removal (destruction of hair follicles) in skin types I-IV, and for soft tissue applications, such as coagulation of soft tissue, e.g., vascular lesions (visible blood vessels).

In contact mode the Uni-Laser 430 can be used for vaporization, ablation, incision, and excision of soft tissue.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician or other practitioner licensed by state law to use or order the use of this device.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use 1
(Per 21 CFR 801.109)

OR Over-The Counter Use

Dianne R. Kachner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993815