2/1/99

K983054

510(k) Summary

Submitter:	Continuum Biomedical A Medical Division of Continuum Electro-Optics, Inc. 6533 Sierra Lane Dublin, CA 94568 Phone: (925) 828-3210 Fax: (925) 556-2222
Contact:	Laurie A. Ridener Regulatory Affairs Officer
Date Summary Prepared:	August 31, 1998
Device Trade Name:	Medlite™ Q-Switched Nd:YAG Laser Medlite™ IV Q-Switched Nd:YAG Laser
Common Name:	Medical laser system
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CRF 878.48
Equivalent Device:	Medlite™ Q-Switched Nd:YAG Laser, Medlite™ IV Q-Switched Nd:YAG Laser (K973719, SE date 12/23/97) ThermoLase LT-100 Nd:YAG Laser Hair Removal System (K950019, SE Date 04-03-95)
Intended Use:	For the removal or lightening of unwanted hair without adjuvant preparation
Comparison:	Equivalent
Nonclinical Performance Data:	None
Clinical Performance Data:	Clinical data was provided to support the use of the Medlite™ Q-Switched Nd:YAG Laser Systems without preparatory lotion to safely remove or lighten unwanted hair without adverse clinical findings.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1999

Ms. Laurie A. Ridener
Regulatory Affairs Officer
Continuum Biomedical
6533 Sierra Lane
Dublin, California 94568

Re: K983054
Trade Name: Medlite™ Q-Switched Nd:YAG Laser
Medlite™ IV Q-Switched Nd:YAG Laser
Regulatory Class: II
Product Code: GEX
Dated: December 3, 1998
Received: December 4, 1998

Dear Ms. Ridener:

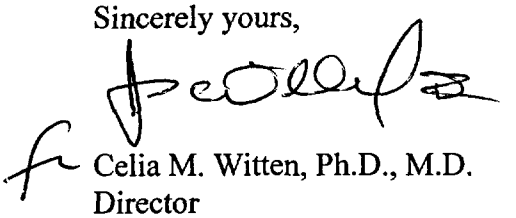
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Premarket Notification - Original Submission
Medlite™ Laser Systems Continuum Biomedical
Revised February 5, 1999

510(k) Number (if known): K983054

Device Name: Medlite™ Q-Switched Nd:YAG Laser
Medlite™ IV Q-Switched Nd:YAG Laser

Indications for Use: For the removal or lightening of unwanted hair in the 1064nm mode only without adjuvant preparation using one or two treatments.

(PLEASE DO NOT 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 K983054

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)