JUN 2 2 2001

510(k) Summary

Submitter:	Continuum Electro-Optics, Inc. 3150 Central expressway Santa Clara, CA 95051
Contact:	Ronald Kohlhardt
Date Summary Prepared:	December 15, 2000
Device Trade Name:	Medlite™ C^3 Q-Switched Nd:YAG Laser
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX
Equivalent Device(s):	Medlite™ Q-Switched Nd:YAG Laser Medlite™ IV Q-Switched Nd:YAG Laser
Intended Use:	• Tattoo Removal • Treatment of Vascular Lesions • Treatment of Pigmented Lesions • Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology
Comparison:	The Medlite™ C^3 Q-Switched Nd:YAG Laser bases its design/construction from the integration of primary subsystems extracted from legally marketed predicate Continuum products. The new device performs and is specified within all product parameters of the predicate devices.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information:	None

K011677

000123

510(k) Number (if known): pending

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Mr. Ronald Kohlhardt
Director, Regulatory Compliance
and Quality Assurance
Continuum Electro-Optics, Inc.
3150 Central Expressway
Santa Clara, California 95051

Re: K011677
Trade/Device Name: Medlite™ C^3 Q-Switched Nd:YAG Laser
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: May 25, 2001
Received: May 30, 2001

Dear Mr. Kohlhardt:

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 legally marketed predicate 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 requirements, 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) 594-4659. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for 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

Device Name: Medlite™ C^3 Q-Switched Nd:YAG Laser.

K011677

Indications for Use:

Tattoo Removal
Treatment of Vascular Lesions
Treatment of Pigmented Lesions
Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

Mark N Millsen

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011677

(Optional Format 1-2-96)

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