SEP -5 1997

K970808

510(k) Summary

Submitter: Continuum Biomedical
A Medical Division of Continuum Electro-Optics, Inc.
6533 Sierra Lane
Dublin, CA 94568
phone: (510) 828-3210
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Contact: Laurie A. Ridener
Regulatory Affairs Officer

Date Summary Prepared: August 1, 1997

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

Common Name: Medical laser system

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CRF 878.48

Equivalent Device: Polytec PI LaseAway Nd:YAG Laser (Lambda Photometrics, Ltd.) (K942622)

Device Description: Medlite IV™ consists of three main components: the power supply used to provide the proper voltage and current to the laser system, the water cooling system used to remove heat from the power supply and the optical bench consisting of the YAG rod, flashlamp, various mirrors, frequency doubler crystal and articulated arm.

The lasing action of the Medlite IV™ occurs when first the flashlamp is excited by a high voltage electrical pulse from the power supply. The excited flashlamp then emits an intense broad-spectrum light. The YAG rod absorbs most of this light and then releases the energy as laser light at 1064nm.

The Q-Switch acts as an extremely high speed shutter and can be set to release the light at pulse rates of 1, 2, 5, and 10 pulses per second or single shot. The frequency doubler can be enabled to change the 1064nm (infrared) light to a second wavelength at 532nm (green).

510(k) Summary (cont'd)

Intended Use:	For incision, excision, ablation, vaporization of soft tissue for general dermatology, as well as at the 1064nm wavelength, dark ink (blue/black) tattoo removal and Nevus of Ota and at the 532nm wavelength, light ink (red) tattoo removal, vascular and pigmented lesions.
Comparison:	Medlite IV™ Q-Switched Nd:YAG Laser and the Polytec PI LaseAway Nd:YAG Laser (Lambda Photometrics, Ltd.) are equivalent in operating parameters, physical characteristics and intended uses.
Nonclinical Performance Data:	None presented at this time.
Clinical Performance Data:	None presented at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP - 5 1997

Re: K970808
Trade Name: Medlite IV™ Q-Switched Nd:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: June 13, 1997
Received: June 16, 1997

Dear Ms. Ridener:

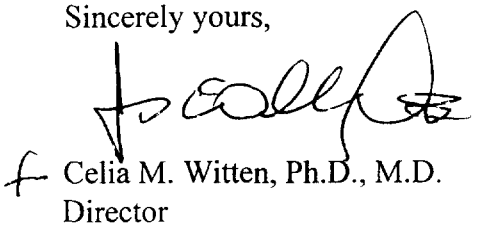
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) 594-4595. 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) Number (if known): K970808

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

Indication for Use: For incision, excision, ablation, vaporization in soft tissue for general dermatology

Specific Indications:

1064nm wavelength:	Dark ink (blue, black) tattoo removal Nevus of Ota
532nm wavelength:	Light ink (red) tattoo removal Vascular lesions Epidermal pigmented lesions

(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 K970808

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

(Optional Format 1-2-96)