APR 2 4 2000

K992597

APPENDIX D

SUMMARY OF SAFETY AND EFFECTIVENESS

LT-100 Q-SWITCHED ND:YAG LASER TREATMENT SYSTEM

This 510(k) summary of safety and effectiveness for the LT-100 Laser Treatment System was prepared using guidance from the Office of Device Evaluation and is intended to comply with the requirements of SMDA 1990.

Applicant:	Focus Medical LLC
Address:	19 Silver Spring Park Ridgefield, CT 06810
Contact Person:	Mr. John Lee President
Telephone:	203-438-1120 203-438-3169 (Fax)
Preparation Date:	April 2000
Device Trade Name:	LT-100 Laser Treatment System
Common Name:	Neodymium: Yttrium, Aluminum; Garnet (Nd:YAG) Laser System; Q-Switched Nd:YAG Laser
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (see: 21 CFR 878.4810). Product Code: GEX Panel 79
Predicate Devices:	ThermoLase SoftLight, Continuum Biomedical, Inc., Medlite™ and Medlite™ IV Q-Switched Nd:YAG Lasers.
Device Description:	The LT-100 Laser Treatment System is a Q-Switched Nd:YAG which emits its energy at 1064 nm.

Intended Use: The LT-100 Laser Treatment System is intended for use:

alone or in combination with an adjuvant lotion for the removal or lightening of unwanted facial or body hair. One or two treatments may be required for lightening or removing unwanted hair without the adjuvant lotion;

in combination with an adjuvant lotion for skin resurfacing (ablation of epidermal skin layers) in dermatology and aesthetic surgery;

dermal pigmented lesions (dermal melanocytosis); and

for tattoo removal (dark and blue inks).

The adjuvant lotion is a suspension of carbon powder in a base of Light Mineral Oil, NF.

The LT-100 will be limited to use by licensed professionals (as provided in 21 CFR 801.109).

Performance Data: None. The specifications and intended uses of the LT-100 Laser Treatment System are the same as or very similar (substantially equivalent) to those of the claimed predicate devices. There are no significant differences between the devices under conditions of intended use.

Because of this, performance data were not required.

Conclusion: The LT-100 Laser Treatment Laser System is substantially equivalent to legally marketed predicate devices, i.e., the ThermoLase SoftLight and the Continuum Biomedical, Inc., Medlite™ and Medlite™ IV Q-Switched Nd:YAG Lasers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2000

Mr. John Lee
President
Focus Medical, LLC
39 Silver Spring Park
Ridgefield, Connecticut 06877

Re: K992597
Trade Name: LT-100 Laser Treatment System
Regulatory Class: II
Product Code: GEX
Dated: February 15, 2000
Received: February 17, 2000

Dear Mr. Lee:

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

APPENDIX B
Rev. 4/2000

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K992597

Device Name: Lorad LT-100 Laser Treatment System

Indications For Use Statement:

The Lorad LT-100 Laser Treatment System is intended for use:

alone or in combination with an adjuvant lotion for the removal or lightening of unwanted facial or body hair. One or two treatments may be required for lightening or removing unwanted hair without the adjuvant lotion;

in combination with the adjuvant lotion for skin resurfacing (ablation of epidermal skin layers) in dermatology and aesthetic surgery;

dermal pigmented lesions (dermal melanocytosis); and

for tattoo removal (dark and blue inks).

The adjuvant lotion is a suspension of carbon powder in a base of Light Mineral Oil, NF.

The Lorad LT-100 Laser Treatment System will be limited to use by licensed professionals (as provided in 21 CFR 801.109).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Donna R. Lochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992597