K974460

APPENDIX G

SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 16 1998

LITE TOUCH ERBIUM LASER TREATMENT SYSTEM

This 510(k) summary of safety and effectiveness for the Lite Touch Erbium 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:	Lorad
Address:	36 Apple Ridge Road Danbury, CT 06810
Contact Person:	Mr. Wally Orlow Vice President, Laser Division
Telephone:	203-731-8400 203-731-8440 (Fax)
Preparation Date: (of the Summary)	November 1997
Device Trade Name:	Lite Touch Erbium Laser Treatment System
Common Name:	Erbium: Yttrium, Aluminum; Garnet (Er:YAG) Laser System; Erbium 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:	Schwartz Electro-Optics, Inc. TriLase 2940 Erbium Laser, and the Continuum Biomedical, Inc., Multilite Erbium Laser and CB Erbium 2.94™ Systems.
Device Description:	The Lite Touch Erbium Laser is an Erbium:YAG laser which emits its energy at 2.94um. See below for additional specifications.
Intended Use:	The Lite Touch Erbium Laser Treatment System is intended for the coagulation, vaporization, ablation, or cutting of soft tissue in dermatology and plastic surgery, including aesthetic surgery and resurfacing. This intended use is the same as or similar to that for the claimed predicate devices.

TriLase Laser:	The SEO Medical TriLase 2940 is indicated for use in a variety of surgical specialties, including cutting (incision/excision), vaporizing and coagulating soft tissues. All soft tissues encountered in surgical procedures are included in this indication, such as, but not limited to, skin, subcutaneous tissue, striated and smooth tissue, muscle, meniscus, mucous membrane, lymph vessels and nodes, organs and glands. Surgical specialties include dermatology, plastic surgery.
Multilite Laser:	The Multilite laser information includes "Cosmetic laser surgery...[is] primarily restricted to applications in dermatology, plastic surgery, and aesthetic surgery.")
	The Multilite Laser was recently found substantially to itself for use in skin resurfacing. The information includes the following specification: At 5 pulses per second and a pulse energy of 2 Joules, the average Power from the laser is 10 watts.
Performance Data:	None. The specifications and intended uses of the Lite Touch Erbium Laser Treatment System are the same 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 Lite Touch Erbium Laser Treatment Laser System is substantially equivalent to legally marketed predicate devices, i.e., the Schwartz Electro-Optics, Inc. TriLase 2940 erbium laser (K954013 and K952554)) and the Continuum Biomedical, Inc. Multilite erbium laser and CB Erbium 2.94™ Er:YAG Laser systems (K961748 and K970394).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 16 1998

Mr. Wally Orlow
Vice President, Laser Division
Lorad Corporation
A Division of Trex Medical Corporation
36 Apple Ridge Road
Danbury, Connecticut 06810

Re: K974460
Trade Name: Lite Touch Erbium Laser Treatment System
Regulatory Class: II
Product Code: GEX
Dated: November 21, 1997
Received: November 25, 1997

Dear Mr. Orlow:

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,

for 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 D

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K974460

Device Name: Lite Touch Erbium Laser System

Indications For Use Statement:

"The Lite Touch Erbium Laser System is intended for the coagulation, vaporization, ablation, or cutting of soft tissue in dermatology and plastic surgery, including aesthetic surgery and skin resurfacing."

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974460