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Attachment I

510(K) Summary
Medical Laser Technologies, LLC MLT Erbium: YAG Laser System

This 510(K) Summary of safety and effectiveness for the MLT Erbium: YAG Laser System is submitted in accordance with the requirements of SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Medical Laser Technologies, LLC
Address:	516 Scott Street Homewood, AL 35209
Contact Person:	Mark Rohrer, Managing Member
Telephone: Telefax:	205-290-8251 205-290-4269
Preparation Date:	July 1, 2003
Device Trade Name: System	Medical Laser Technologies, LLC, MLT Erbium: YAG Laser
Common Name:	Erbium:YAG laser devise
Classification Name:	Instrument, Powered, Laser 79-GEX 21 CFR 878-48
Legally Marketed Predicate Device	Schwartz Electro-Optics TriLase 2940, K#954013 Cell Robotics Er:YAG Laser System, K#970461 Asceplion-Meditec Dermastar Er:YAG Laser System, K#014057
Description of the Device	The Medical Laser Technologies, LLC MLT Erbium: YAG Laser System is an Er:YAG laser producing emission at a wavelength of 2940 nm. The laser consist of two interconnected sections: The cabinet which houses the power supply, the cooling system and the electronics, and; the umbilical cables and the hand piece, which houses the laser.
Intended Use of the Device:	The MLT Erbium: YAG Laser System device is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology.

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INTRODUCTION

The Medical Laser Technologies, LLC MLT Erbium: YAG Laser System is intended for superficial skin ablation resulting in skin dermabrasion and the treatment of wrinkles. In addition, the system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery, (including aesthetic surgery), oral surgery and opthalmology. The laser system is designed for reliability, for long life, and ease of use. As a result, no maintenance should be required other than cleaning the instrument and an annual calibration check.

As with any laser system, appropriate care must be taken to ensure proper and safe use. **This entire manual should be thoroughly reviewed before operating the instrument. Further, the physician should attend a certified laser-training course before using the Medical Laser Technologies, LLC MLT Erbium: YAG Laser System for medical treatment.**

All users should become familiar with the requirements for safe use of medical laser systems as described in the American National Standards Institute (ANSI) publications, American National Standard for the Safe Use of Lasers in Health Care Facilities (ANSI Z126.3-1988), AND, American National Standard for the Safe Use of lasers (ANSI Z136.1-1986). The information in this manual is provided in accordance with these Standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

Mr. Mark Rohrer
Managing Member
Medical Laser Technologies, LLC
516 Scott Street
Homewood, Alabama 35209

Re: K032599
Trade/Device Name: Medical Laser Technologies, LLC MLT Erbium:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: July 7, 2003
Received: August 27, 2003

Dear Mr. Rohrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

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

INDICATION FOR USE STATEMENT

510(K) Number: K032599

Device Name: Medical Laser Technologies, LLC MLT Erbium: YAG Laser System

Indications for Use:

The MLT Erbium: YAG Laser System device is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery), oral surgery, and ophthalmology.

(Please do not write below this line – continue on another page if needed)

Miriam C. Provost

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

510(k) Number K032599

Concurrence of CDRH, Office of Device Evaluation (OD

Prescription Use ✓ OR Over-the-Counter Use ____
(per 21 CFR 801.109)