MAY 27 1999

K990902

APPENDIX E

510(k) SUMMARY
MEDICAL LASER TECHNOLOGIES LTD
MLT R694 RUBY LASER SYSTEM
Q-SWITCHED MODE

This 510(k) summary of safety and effectiveness for the Medical Laser Technologies Ltd. MLT R694 Ruby Laser System operating in the Q-Switched Mode is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: MEDICAL LASER TECHNOLOGIES LTD

Address: Unit 15
Belleknowes Industrial Estate
Inverkeithing
Fife KY11 1HZ
United Kingdom

Contact Person: David Hamilton
Managing Director

Telephone: 011 44 1383 411555
Facsimile: 011 44 1383 411666

Preparation Date: March 1999

Device Name: MLT R694 Ruby Laser System

Common Name: Ruby Laser, Normal Pulse or Q-Switched Mode

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

Legally marketed: LaseAway Long Pulse and Q-Switched Ruby Laser, MM-Ruby Laser; Spectrum RD 1200; Candela AlexLAZR.

Description: The MLT R694 laser operates as a normal pulse or as a Q-Switched ruby laser which emits a beam of coherent light at 694 nanometers. In the Q-Switched mode the beam has a much shorter pulse duration than in the normal or long pulse mode. The specifications for the normal or long pulse mode remain the same as described in K980187.

Intended Use: The MLT R694 Ruby Laser System in the Q-Switched mode is indicated for cutting, vaporization, or ablation of soft tissue. This includes tatoo removal and treatment of benign pigmented lesions.

The intended uses of the MLT R 694 ruby operating in normal or long pulse mode remain the same as described in K980187.

Comparison to: The specifications of the MLT R694 laser in the Q-Switched mode are the same as or very similar to those of legally marketed lasers such as the LaseAway Long Pulse and Q-Switched Ruby Laser, the MM-Ruby Laser; the Spectrum RD 1200, and the Candela AlexLAZR

Performance Data: None. The specifications and intended uses of the MLT R694 ruby system laser operating in the Q-Switched mode are the same or very similar to those of the claimed predicate devices.

Because of this, performance data were not required.

CONCLUSION: When operating in the Q-Switched mode the MLT R694 is substantially equivalent to legally marketed predicate devices, e.g., ruby and alexandrite lasers, operating in the Q-Switched mode.

The MLT R694 ruby laser system, operating in the normal mode, has been found substantially equivalent to legally marketed devices (K980187); the characteristics, specifications, and intended uses of the MLT R 694 operating in this mode are not affected by the modification to allow use in the Q-Switched mode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1999

Mr. David Hamilton
Managing Director
Medical Laser Technology, Ltd.
Unit 15
Belleknowes Industrial Estate
Inverkeithing
Fife KY11 1HZ
United Kingdom

Re: K990902
Trade Name: MLT R694 Ruby Laser System
Regulatory Class: II
Product Code: GEX
Dated: March 16, 1999
Received: March 18, 1999

Dear Mr. Hamilton:

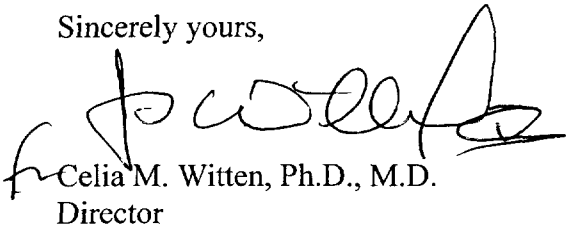
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K990902

Device Name: MLT R694 RUBY LASER SYSTEM

Indications For Use Statement:

The MLT R694 Ruby Laser System (operating in the Q-Switched mode) is indicated for cutting, vaporization, or ablation of soft tissue. This includes tatoo removal and treatment of benign pigmented lesions.

The MLT R694 Ruby Laser System is restricted to sale to or use by licensed professionals in the United States

(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)

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(Division Sign-Off)
Division of General Restorative Devices K990902
510(k) Number