K980187

APR - 3 1998

APPENDIX E

510(k) SUMMARY
MEDICAL LASER TECHNOLOGIES LTD
MLT R694 RUBY LASER SYSTEM

This 510(k) summary of safety and effectiveness for the diode surgical laser 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 4 Belleknowes Industrial Estate Inverkeithing Fife KY11 1HY United Kingdom
Contact Person:	David Hamilton Managing Director
Telephone:	+44 1383 411555 +44 1383 411666 (Fax)
Preparation Date: (of the Summary)	January 1998
Device Name:	MLLT R694 Ruby Laser System
Common Name:	Ruby Laser, Long or Normal Pulse
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 predicate devices:	EpiLaser^{R}, Chromos 694, and the EpiTouch lasers among others.
Description of the Device:	The MLT R694 laser is a normal or long pulse ruby laser which emits a beam of coherent light at 694 nanometers.
Indications for Use:	The MLT R694 laser is intended for the removal of unwanted body hair.

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Comparison to: The specifications of the MLT R694 laser are the same as or very similar to those of legally marketed lasers such as the EpiLaser^{R}, the Chromos 694, and the EpiTouch.

Performance Data: None. The specifications and indications for use of the MLT R694 ruby system laser are the same or very similar to those of the claimed predicate devices.

Because of this, performance data were not required.

CONCLUSION: Based on the similarities of specifications and indications for use for hair removal, Medical Laser Technologies Ltd. believes that the MLT R694 ruby laser system is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1998

Mr. David C. Hamilton
Managing Director
Medical Laser Technologies Limited
Unit 4
Belleknowes Industrial Estate
Inverkeithing, Fife KY11 1HY
United Kingdom

Re: K980187
Trade Name: MLT R694 Ruby Laser System
Regulatory Class: II
Product Code: GEX
Dated: January 16, 1998
Received: January 20, 1998

Dear Mr. Hamilton:

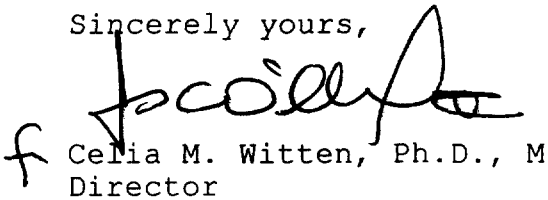
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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 B

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K980187

Device Name: MLT R694 RUBY LASER SYSTEM

Indications For Use Statement:

The MLT R694 Ruby Laser System is intended to remove unwanted body hair.

Patient selection criteria include patients with skin types 1-4.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980187