K063574

APPENDIX C

SUMMARY OF SAFETY AND EFFICACY
(Per 21 CFR Part 807.92)

I. General Information

JAN 2 9 2007

Device Generic Name:	Low Level Therapeutic Laser
Trade Name:	Luminex LL Laser System
Device Classification:	Class II, Performance Standards 21CFR Part 890.5500 - Infrared Lamp, Non-heating
Product Code:	NHN
Applicant Name and Address:	Medical Laser Systems, Inc. 20 Baldwin Drive Branford, CT 60405 203 / 481-2395 Brian D. Richardson, President
Key Contact:	Miki Kolton Regulatory Consultant Greenberg, Traurig, LLP 800 Connecticut Ave. NW Suite 500 Washington, DC 20006 (202)331-3100 mkolton@gtlaw.com
510(k) Number:	Pending

II. Device Description

The Luminex LL System is a non-thermal, non-invasive, low energy infrared laser, therapeutic medical device that is intended for use as an adjunctive treatment for the temporary relief of hand and wrist pain associated with carpal tunnel syndrome. The Luminex Laser Therapy System incorporates an AC or battery powered Control Unit and a hand-held laser diode probe incorporating three 30 milliwatt (mW) Gallium Aluminum Arsenide (GaAlAs) laser diodes delivering a total output power of 90mW at the 830 nanometer (nm) wavelength.

III. Indication for Use

The Luminex Laser Therapy System is a non-heating, infrared lamp indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

IV. Predicate Devices

The Luminex LL Laser System is substantially equivalent to other low level therapeutic lasers currently in commercial distribution. These predicate devices include the Microlight Corporation of America, Inc., MicroLight 830 Laser System (K010175), the Acculaser, Inc. Acculaser Pro Low Level Laser System (K020657), and the Meridian Co., Ltd., Lapex 2000 (K034009).

V. Summary of the Technical Characteristics of the Laser System as Related to the Referenced Predicate Devices.

The Luminex LL Laser System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices use infrared diodes to emit invisible photonic energy to tissue. The Luminex LL Laser System and the aforementioned predicate devices have the same intended uses and similar technical and performance characteristics.

VI. Testing

Testing of the System includes functional performance testing and electrical safety testing. The Luminex LL Laser System is manufactured to comply with the FDA's Quality System Regulations and applicable standards for light emitting medical devices.

VII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the Luminex LL Laser System has the equivalent intended uses, with similar technical characteristics. The Luminex LL Laser System is designed to comply with the generally accepted therapeutic laser performance specifications as an adjunctive treatment for the relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

The Luminex LL Laser System performs as intended and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medical Laser Systems, Inc.
% Greenberg, Traurig, LLP
Mr. Miki Kolton
Regulatory Consultant
800 Connecticut Avenue, NW
Suite 500
Washington, District of Columbia 20006

JAN 2 9 2007

Re: K063574
Trade/Device Name: Luminex LL Saser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp.
Regulatory Class: Class II
Product Code: NHN
Dated: November 28, 2006
Received: November 29, 2006

Dear Mr. Kolton:

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.

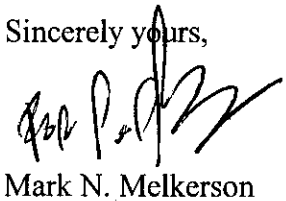
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. In response to question #1 regarding indications for use: below is the revised page 16, "Indications for Use Statement" for your review. The indications for use have been revised to reflect the indications for use of the chosen predicate devices.

(Appendix A, Page 16)

APPENDIX A

Indications for Use Statement

510(k) Number (if known): ~~Pending~~ K063574

Device Name:

Luminex LL Laser System

Indication for Use:

Probe	Indications for Use
830nm	**Adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome**

Prescription Use: X **AND/OR Over the Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODpE)

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

510(k) K063574