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APPENDIX D

SUMMARY OF SAFETY AND EFFICACY

Advanced Medical Technologies, Inc.
Omega Xp Therapeutic Laser System
(as per 21 CFR Part 807.92)

November 11, 2004

I. GENERAL INFORMATION

Device Generic Name:	Low Level Laser Therapy (LLLT) Therapeutic Laser
Trade Name:	Omega XP Laser System
Device Classification:	Class II, Performance Standards 21CFR Part 890.5500 - Infrared Lamp, Non-heating
Product Code:	NHN
Applicant Name and Address:	Advanced Medical Technologies 101 Waterside Drive Centerville, MA 02632 508 / 790-9300 Neil Camera, President lasertherapeutics@comcast.net
510(k) Number:	K043353

II. DEVICE DESCRIPTION

The Omega Xp Laser System is a non-invasive, portable therapeutic medical laser designed to deliver light energy to the target tissue. The System operates by either AC or battery power and can be used with a variety of laser probes. The Omega Xp Laser System is intended to emit energy in the infrared spectrum to provide temporary relief of pain associated with rotator cuff tendonitis.

The Omega Xp Laser System is comprised of a Base Unit and select Laser Probes. The Base Unit houses the electronics, circuits and controls to power the Laser Probes. The Laser Probes are connected to the Base Unit by an umbilical cord. The Laser Probes house the laser diode and circuitry to deliver the light energy to the designated treatment areas.

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III. INDICATIONS FOR USE

The Omega Xp Laser System is indicated for use as an adjunctive treatment modality to provide temporary relief of pain associated with rotator cuff tendonitis.

IV. Predicate Devices

Predicate devices to the Omega Xp Laser System are the Photo Thera, Inc. Acculaser Pro 4 (K023060) and the Stargate International, Inc. Excalibur Light Therapy System (K041530).

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

The Omega System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared diodes to emit infrared light energy to human tissues. The Omega System and the named 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 Omega Xp Laser System is manufactured to comply with the following international standards:

ISO 9000:2000
EN46001
Directive 89/336 regarding electromagnetic compatibility

VII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the Omega XP Laser has the same intended uses, with similar functional and performance characteristics. The System is designed to comply with applicable performance standards promulgated by Federal Food and Drug Administration, such as 21 CFR 1010 and 1040. Further evidence of the safety and efficacy of the Omega System was assessed by the randomized, blinded clinical trial conducted.

The Omega Xp Laser System performs as intended and do not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 - 2005

Advanced Medical Technologies Incorporated
C/o Ms. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services Incorporated
12101 Cullen Boulevard # A
Houston, Texas 77047

Re: K043353
Trade/Device Name: Omega Xp laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-heating for adjunction use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: March 31, 2005
Received: April 4, 2005

Dear Ms. Heinrich:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX A

Indications for Use Statement

510(k) Number (if known): K043353

Device Name:

Advanced Medical Technologies, Inc.
Omega Xp Laser System

Indications for Use:

The Omega Xp Laser System is intended for use as an adjunctive treatment modality to provide temporary relief of pain associated with rotator cuff tendonitis.

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 Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K043353