K053473

APPENDIX B

SUMMARY OF SAFETY AND EFFICACY

Maestro MDTL Therapeutic Laser System (as per 21 CFR Part 807.92)

I. GENERAL INFORMATION

Device Generic Name: Infrared Lamp

Trade Name: Maestro MDTL Laser System

Device Classification: Class II, Performance Standards
21CFR Part 890.5500 - Infrared Lamp,

Product Code: ILY

Applicant Name and Address: Advanced Medical Technologies, Inc.
101 Waterside Drive
Centerville, MA 02632
508 / 790-9300
Neil Camera, President
lasertherapeutics@hotmail.com

510(k) Number: Pending

II. DEVICE DESCRIPTION

The Maestro MDTL Laser System is a non-invasive, portable therapeutic medical laser designed to deliver light energy to the target tissue. The System operates by AC power and can be used with a variety of laser probes.

The Maestro MDTL Laser System is comprised of a Base Unit and select Laser Probes. The Control Unit houses the electronics, circuits and controls to power the Laser Probes. The Laser Probes are connected to the Control Unit by a cable, which plugs into the rear of the Control Unit. The Laser Probes house the laser diode and circuitry to deliver the light energy to the designated treatment areas.

III. INDICATIONS FOR USE

The Maestro MDTL Laser System is intended to emit energy in the visible red & infrared spectrums to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

IV. Predicate Devices

The Maestro MDTL Laser System is substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. Representative predicate devices to the Maestro MDTL Laser System include, but are not limited to, the Light Force Therapy, Inc. Super Nova and Acubeam Systems (K001179), Medical Laser Therapeutics, LP MLT-1000 IR Laser System (K033986), the Meditech International Inc BioFlex Professional Therapy System (K023621), the Thor International DDII Laser System (K033923) and the Chattanooga Group Vectra Genisys Laser System (K040662).

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

The Maestro MDTL Laser System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain. The Maestro 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 Maestro MDTL 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 Maestro MDTL 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. The Maestro MDTL 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

FEB 3 2006

Advanced Medical Technologies, Inc.
c/o Ms. M. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services, Inc.
12101-A Cullen Blvd.
Houston, Texas 77047-2951

Re: K053473
Trade/Device Name: Maestro MDTL Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: December 12, 2005
Received: December 14, 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" (21 CFR 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,

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

Enclosure

APPENDIX C

Indications for Use

510(k) Number (if known): ~~Pending~~ K053473

Device Name:

Maestro MDTL Laser System

Indications for Use:

The Maestro MDTL Laser System is intended to emit energy in the visible red & infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

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)

Barbara Smith MD for MKM

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

510(k) Number K053473