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Attachment 4

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the Palomar SLP 1000 ThermaPulse™ is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

Applicant:	Palomar Medical Technologies, Inc.
Address:	82 Cambridge St. Burlington, MA 01803
Contact Person:	Marcy Moore
Telephone:	919-363-2432
Preparation Date:	December 12, 2002
Device Trade Name:	Palomar ThermaPulse™
Common Name:	ThermaPulse™
Classification Name:	Infrared Heating Lamp (see: 21 CFR 890.5500).
Legally-Marketed Predicate Device:	K020851-TDP Heat Lamp; K021956, MHS Med Light 1000; K003538, TDP CQ-27 Heat Lamp
System Description:	The ThermaPulse™ delivers infrared light with a wavelength of 810 +/-20 nm. The complete system consists of a laser unit, a footswitch, and a ThermaPulse™ handpiece connected to the laser unit with an umbilical. In standard use, the ThermaPulse is positioned at an average distance of 23 cm from the treatment area. The ThermaPulse is equipped with a fan to offer greater patient's comfort. System parameters and other features are controlled from the user interface panel on top of the laser unit, which provides an interface to the system computer.

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Intended Use of the Device:	The ThermaPulse™ at the power settings in the range of 5-50 Watts (power density 75-500 mW/cm2) is intended to emit energy in the 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, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the ThermaPulse™ may also help muscle spasms, minor sprains and strains, and minor muscular back pain.
Performance Data:	The differences in the specifications of the ThermaPulse™ and the predicate devices do not result in different performance or raise new questions of safety or efficacy.
Conclusion:	Based on the foregoing, the ThermaPulse™ is substantially equivalent to the legally-marketed claimed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2003

Ms. Marcy Moore
Manager of Clinical Studies
Palomar Medical Technologies, Inc.
131 Kelekent Lane
Cary, North Carolina 27511

Re: K024179
Trade/Device Name: Palomar ThermaPulse™
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared heating lamp
Regulatory Class: II
Product Code: ILY
Dated: March 5, 2003
Received: March 6, 2003

Dear Ms. Moore:

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 (301) 594-4659. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K024179

Device Name: ThermaPulse™

Indications for Use:

The ThermaPulse™ at the power settings in the range of 5-50 Watts is intended to emit energy in the 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, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the ThermaPulse™ may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use ____

(per 21 CFR 801.109)

for Mark A. Melkerson

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

510(k) Number K024179