510(k) SUMMARY

MAY 1 4 2003

L600® Photoepilation System

K030490

Submitter's name, address, telephone number, contact person and Date

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Date Prepared : January 28, 2003

Name of Device

Device Trade Name: L600® system
Common name: L600® Intense Pulsed Light Hair Removal System
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code: GEX
Regulation Number : 878 4810

Predicated Devices

Palomar Medical Technologies, Inc : Estelux™ ; K020453
Radiancy Spa Touch™; K020856

System Description

The L600® is a non-coherent light-based device designed for photothermal removal of unwanted hair.

Intended Use

The L600® is a non-coherent light-based device designed for photothermal removal of unwanted hair of the face and the body in skin types I to IV through targeting of melanin in the hair follicle. The L600® is intended to effect permanent hair reduction.

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Comparing technical characteristics/ Performance Data

The differences in the specification of the L600® and the predicate device do not result indifferent performance or raise any new questions of safety or efficacy. The clinical data demonstrated that the device can be used effectively and safely by a trained skin professional.

Summary

Based on the foregoing, we believe that the L600® is substantially equivalent to the legally marketed predicate devices, the Estelux™ or the Spa Touch™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2003

Mr. Pascal DANET
Applications Specialist
A&M Technology
28, rue de la Tremoille
F 75008 PARIS

Re: K030480
Trade/Device Name: System L600®
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 3, 2003
Received: February 13, 2003

Dear Mr. Danet:

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,

Miriam C. Provost

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

Applicant: A&M Technology SAS

510(k) Number (if known): K030480

Device Name: System L600®

Indications for Use:

The L600® is a non-coherent light-based device designed for photothermal removal of unwanted hair of the face and the body in skin types I to IV through selective targeting of melanin in the hair follicle. The L600® is intended to effect permanent hair reduction.

According to the Food and Drug Administration, permanent hair reduction is defined as a long term and stable reduction in number of hair follicle re-growing after a treatment regime. The number of hair re-growing must be stable over time greater than the duration of a complete growth cycle of hair follicles according to body location.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K030480