

K060839

510(k) Summary
ABC Hair Removal System

DEC - 7 2006

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

1. SUBMITTER'S INFORMATION

NAME: Palomar Medical Technologies, Inc.

ADDRESS: 82 Cambridge Street
Burlington, MA 01803
Phone: (781) 993-2300
Fax: (781) 993-2330

CONTACT: Sharon Timberlake, RAC, CCRA
Director, Clinical & Regulatory Affairs

DATE PREPARED: October 26, 2006

2. DEVICE INFORMATION

TRADE/PROPRIETARY NAME: ABC Hair Removal System

COMMON/USUAL NAME: Light Based Hair Removal System

CLASSIFICATION NAME: Laser surgical instrument for use in general and
plastic surgery and in dermatology
(21 CFR §878.4810)

PRODUCT CODE: GEX

3. PREDICATE DEVICES

SpaTouch® PhotoEpilation System (K020856)
Radiancy (Israel) Ltd.

Spectra Hair Removal Laser (K052848)
SpectraGenics, Inc.

Palomar SLP™ 1000 (K013028)
Palomar Medical Technologies, Inc.

4. INTENDED USE

The ABC Hair Removal System is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments.

5. DEVICE DESCRIPTION

The ABC Hair Removal System is composed of a base unit, umbilical cord, handpiece, chiller system with chiller coolant, cleaning wipes, ABC lubricant, power supply and safety components. Details are provided in the Device Description Section of this submission.

6. PERFORMANCE & CLINICAL DATA

The device complies with the following U.S. Food and Drug Administration performance standards: 21 CFR §1040.10 & 1040.11. Clinical data was collected in a prospective clinical study to support the safety and effectiveness of the ABC Hair Removal System for over-the-counter use. The clinical studies demonstrated that the ABC System functions as intended with no serious adverse events.

7. SUBSTANTIAL EQUIVALENCE

The ABC Hair Removal System is substantially equivalent to its predicate devices when intended for use for hair removal. The data in this 510(k) notification demonstrate that the ABC System shares the same intended use, and similar design features and functional features, and therefore is substantially equivalent to its predicate devices. Details are provided in the Substantial Equivalence Section of this submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2008

Palomar Medical Technologies, Inc.
% Ms. Sharon Timberlake, RAC, CCRA
Director of Regulatory Affairs
82 Cambridge Street
Burlington, Massachusetts 01803

Re: K060839

Trade/Device Name: ABC Hair Removal System

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: OHT

Dated: July 24, 2006

Received: July 25, 2006

Dear Ms. Timberlake:

This letter corrects our substantially equivalent letter of December 7, 2006.

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 (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 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

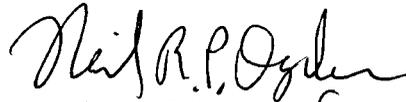
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue 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/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): K060839

Device Name: ABC Hair Removal System

Indications for Use:

The ABC Hair Removal System is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number

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OR

Over-The-Counter Use X

Prescription Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)