K020856 1/2

JUN 13 2002

510(k) SUMMARY

Radiancy (Israel) Ltd.'s SpaTouch® PhotoEpilation System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Radiancy (Israel) Ltd.
9 Gan Ravve Street
Industrial Park
Yavne
Israel
Telephone: +972-8-9438010
Facsimile: +972-8-9438020

Contact Person: Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109
Telephone: (202) 637-5794
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Email: JSKahan@HHLaw.com

Date Prepared: March 12, 2002

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name:	SpaTouch® PhotoEpilation System
Common Name:	Pulsed Light Hair Removal System
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR § 878.4810)
Address of Manufacturing Facility:	Radiancy (Israel) Ltd. 9 Gan Ravve Street Industrial Park Yavne Israel
Establishment Registration Number:	9616256
Owner/operator number:	9040071

K020886 2/2

Predicate Devices

Radiancy (Israel) Ltd. DeLight II Hair Removal System

Intended Use / Indications for Use

The SpaTouch is intended for removal of unwanted hair by using a selective photothermal treatment. The device is generally indicated for dermatological use. The SpaTouch is specifically indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional.

Technological Characteristics and Substantial Equivalence

The SpaTouch and its predicate device are intended for removal of unwanted hair by using a selective photothermal treatment. The device is generally indicated for dermatological use. The SpaTouch is specifically indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional. With the exception of contact switches added to the handpiece, the SpaTouch is the exact same device as the previously cleared DeLight II device. The only differences between the cleared DeLight II and the SpaTouch are the addition of the contact switches to the handpiece and the expanded indications for use. Neither of these differences raises new issues of safety or effectiveness. Thus, the SpaTouch can be found substantially equivalent.

Performance Data

Clinical data demonstrated that the device can be used safely and effectively under the supervision of a health professional.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2002

Radiancy (Israel) Ltd.
c/o Mr. Jonathan S. Kahan, Esq.
Hogan & Hartson L.L.P.
555 Thirteenth Street, N. W.
Washington, D.C. 20004-1109

Re: K020856
Trade Name: SpaTouch® PhotoEpilation System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 14, 2002
Received: May 14, 2002

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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.

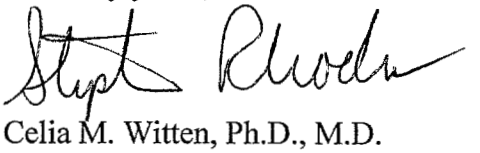
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,



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 Form

510(k) Number (if known): K020856

Device Name: **SpaTouch® PhotoEpilation System**

Indications for Use:

The SpaTouch PhotoEpilation System is intended for removal of unwanted hair by using a selective photothermal treatment. The device is generally indicated for dermatological use. The SpaTouch is specifically indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K020858

Prescription Use __X__ OR Over-The-Counter Use____

(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)