K052991

FEB 1 2006

510(k) SUMMARY

Radiancy (Israel) Ltd. Radiancy Facial SkinCare Device

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

Manufacturer:

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

Contact Person:

Margaret Fourte
Director, Clinical and Regulatory Affairs
Radiancy, Inc.
40 Ramland Road
Orangeburg, NY 10972
Telephone: (845) 398-1647
Facsimile: (845) 398-1648
Email: margaret@radiancy.com

Date Prepared: January 20, 2006

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: Radiancy Facial SkinCare Device

Common Name: Pulsed Light System and Light Unit Assembly

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 C.F.R. § 878.4810)

Manufacturing Facility:

Radiancy (Israel) Ltd.
9 Gan Rave Street
Industrial Park
Yavne, Israel

Establishment Registration Number: 9616256

Owner/operator number: 9040071

K052991

Predicate Devices

Radiancy, Inc. SPR System (K033181)

Danish Dermatologic Development A/S Ellipse I^{2}PL™ (K043255)

Device Description

The Radiancy Facial SkinCare Device is a pulsed-light, manually controlled system designed to treat benign pigmented lesions.

Intended Use / Indications for Use

The Facial SkinCare Device is intended for use in dermatology. The Facial SkinCare Device is specifically indicated to treat benign pigmented lesions, including, but not limited to solar lentigines, ephilides (freckles), and mottled pigmentation in patients with Fitzpatrick skin types I-V.

Technological Characteristics

The Facial SkinCare Device that is the subject of this 510(k) notice is similar to devices already cleared to treat benign pigmented lesions.

Substantial Equivalence

The Radiancy Facial SkinCare Device has the same intended use and one of the same indications for use, same principles of operation and same technological characteristics as the Radiancy SPR System and the Ellipse I^{2}PL™, which have already been cleared to treat benign pigmented lesions. The minor differences between the Radiancy Facial SkinCare Device and the predicates do not raise new issues of safety and effectiveness. Thus, the Radiancy Facial SkinCare Device is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2006

Radiancy (Israel) Ltd.
c/o Ms. Margaret Fourte
Director, Clinical and Regulatory Affairs
Radiancy, Inc.
40 Ramland Road South, Suite 10
Orangeburg, New York 10962

Re: K052991
Trade/Device Name: Radiancy Facial SkinCare Device
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: December 22, 2005
Received: December 23, 2005

Dear Ms. Fourte:

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,

Barbara Bucher

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

Enclosure

Indication for Use Form

510(k) Number (if known): K052991

Device Name: **Radiancy Facial SkinCare Device**

Indications for Use:

The Radiancy Facial SkinCare Device is intended for dermatological use. The Facial SkinCare Device is specifically intended to treat benign pigmented lesions, including, but not limited to solar lentigines, ephilides (freckles), and mottled pigmentation in patients with Fitzpatrick skin types I-V.

Prescription Use _X_ OR Over-The-Counter Use__
(Per 21 C.F.R. 801.109)

(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 K052991