OCT 2 4 2003

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510(k) SUMMARY

Radiancy (Israel) Ltd.'s SPR System

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

Radiancy (Israel) Ltd.
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Yavne
Israel
Telephone: +972-8-9438010
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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:

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name:	SPR™ System
Common Name:	Pulsed Light 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

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Establishment Registration Number: 9616256

Owner/operator number: 9040071

Predicate Devices

Radiancy's SkinStation® System (K030897)

Intended Use / Indications for Use

The SPR is a pulsed light device intended for providing light therapy to the body and specifically indicated for treatment of pigmented and vascular lesions.

Technological Characteristics and Substantial Equivalence

The SPR is a pulsed light device intended for providing light therapy to the body and specifically indicated for treatment of pigmented and vascular lesions. The SPR has the same intended use, with similar indications for use, and is technologically identical to the cleared SkinStation with respect to the operation and function of the SkinStation's pigmented and vascular lesions module.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2003

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

Re: K033181
Trade/Device Name: SPR™ 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: GEX
Dated: September 30, 2003
Received: October 1, 2003

Dear Mr. Kahan:

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. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

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): K033181

Device Name: **SPR™ System**

Indications for Use:

The SPR is a pulsed light device intended for providing light therapy to the body and specifically indicated for treatment of pigmented and vascular lesions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use____

(Per 21 C.F.R. 801.109)

Miriam C. Provost

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

510(k) Number K033181

(Optional Format 1-2-96)