

**JUN 19 2003**

**510(k) SUMMARY**

**Radiancy (Israel) Ltd.'s SkinStation™ System**

K030897

**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

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Contact Person: Jonathan S. Kahan, Esq.  
Regulatory Counsel  
Hogan & Hartson L.L.P.  
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Date Prepared: March 19, 2003

**Name of Device and Name/Address of Sponsor**

Trade/Proprietary Name:	SkinStation™ 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

Establishment Registration Number: 9616256  
Owner/operator number: 9040071

### **Predicate Devices**

Radiancy's SpaTouch Hair Removal System  
Lumenis IPL Quantum SR  
Medical Bio Care Sweden's Prolite  
Palomar's Estelux.

### **Intended Use / Indications for Use**

The SkinStation is a pulsed light device intended for hair removal and for treatment of pigmented and vascular lesions.

### **Technological Characteristics and Substantial Equivalence**

The SkinStation is a pulsed light device intended for hair removal and treatment of pigmented and vascular lesions. When operated in the hair removal mode, the Skin Station is identical to the previously cleared SpaTouch, except that it is now housed with the SPR module for treating pigmented and vascular lesions. When operated in the pigmented and vascular lesions mode (*i.e.*, using the SPR handpiece), the SkinStation has the same intended use, with similar indications for use, and is technologically similar to the cleared Quantum, with a few exceptions which do not raise new issues of safety and effectiveness. In addition, the SkinStation has the same intended use, with similar indications for use, and is technologically similar to the previously cleared MBC's Prolite and Palomar's Estelux when operated in the SPR mode



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K030897

Trade/Device Name: SkinStation™ 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: March 21, 2003  
Received: March 21, 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. 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

Indications for Use Form

510(k) Number (if known): K 030897

Device Name: SkinStation™ System

Indications for Use:

The SkinStation is a pulsed light device intended for hair removal and 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

(Optional Format 1-2-96)

510(k) Number K 030897