

DEC 27 1999

K992482

510(k) Summary

Radiancy (Israel) Ltd.'s DeLight™ II HR System

Submitter's name: Radiancy (Israel) Ltd.

Submitter's address: Lev Hatamar Building
4 Pekeris St.,
Rabin Science Based Industrial Park
Rehovot 76702
ISRAEL

Telephone: +972-8-9477374

Fax: +972-8-9477373

Contact Person: Simona Konkol, Director of Regulatory Affairs.

Preparation Date: July 22, 1999

Device Trade Name: DeLight™ II HR System

Common Name: Light Based Hair Removal System

Classification Name: Laser Surgical Instrument pursuant to 21 CFR 878.4810.

Predicate Device:

EpiLight® Hair Removal System, manufactured by ESC Medical Systems Ltd. of Yokneam, Israel, 510(k) #K963249.

Description of the Device:

The DeLight™ II HR System is a light-based medical device intended for removal of unwanted hair by using a selective photothermal treatment.

Intended Use:

The DeLight™ II HR System is a light-based medical device intended for removal of unwanted hair by using a selective photothermal treatment. The device is specifically indicated for dermatological use.

Comparison of Technological Characteristic:

Radiancy has performed a detailed side-by-side comparison of the technical specification of the predicate device and the DeLight™ II HR System. The results have shown that the system specifications of the DeLight™ II HR System are substantially equivalent to the technical specifications of the cleared EpiLight® System. The DeLight™ II HR System has few differences from the predicate device, for example, the DeLight™ II HR operates at lower fluence levels than the predicate device and uses one pulse light while the predicate device uses multiple pulses with variable pulse width. The predicate device is computer controlled while the DeLight™ II HR System is controlled manually by the user. However, these minor differences do not raise new questions of safety or efficacy, thus the DeLight™ II HR System is substantially equivalent to its predicate device.

Clinical Performance Data:

The DeLight™ II HR System has been studied in an IRB approved human clinical trial, in which various skin types and various hair colors were treated by the DeLight™ II HR System. Clearance rates and occurrence of side effects were examined. The data was compared to published data on the clearance and side effects of the predicate device. The clinical results and the comparison to the predicate device demonstrate that the DeLight™ II HR System is safe and effective. Thus, the DeLight™ II HR System is substantially equivalent to the predicate device.

Non-Clinical Performance Data: None required.



DEC 27 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992482
Trade Name: DeLight II HR System
Regulatory Class: II
Product Code: GEX
Dated: December 1, 1999
Received: December 1, 1999

Dear Mr. Kahan:

We have reviewed your Section 510(k) 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



sw James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510 (k) Number: New Submission K 992482

Device Name: DeLight™ II HR System

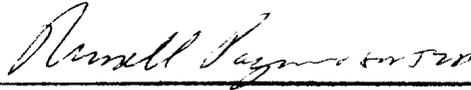
Indications for use:

The DeLight™ II HR System is intended for removal of unwanted body and/or facial hair in adults.

The System is specifically indicated for dermatological use by physicians and healthcare professionals.

(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 Devices

510(k) Number K992482

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____