

K041994 1/3

OCT 6 - 2004

**510(k) SUMMARY**

**CURELIGHT LTD.'S MULTICLEARXL MULTIWAVELENGTH  
TARGETED PHOTOTHERAPY SYSTEM**

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

CureLight Ltd.  
2 Ha'ilan Street  
Northern Industrial Zone, POB 247  
Or Akiva 30600, Israel  
Phone: 011-972-4610-0969  
Facsimile: 011-972-4626-0733

Contact Person: Yoram Harth, M.D.

Date Prepared: July 15, 2004

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

MultiClearXL Multiwavelength Targeted Phototherapy System  
CureLight Ltd.  
2 Ha'ilan Street  
Northern Industrial Zone, POB 247  
Or Akiva 30600, Israel

**Common or Usual Name**

Phototherapy System

**Classification Name**

Ultraviolet Lamp for Dermatologic Disorders

**Predicate Devices**

| Device Name:  | Manufacturer: |
|---|---------------|
| MultiClear Multiwavelength Targeted Phototherapy System | CureLight     |
| ClearLight  | CureLight     |
| ClearTouch Acne Therapy System                          | Radiancy      |

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

The MultiClearXL Multiwavelength Targeted Phototherapy System ("MultiClearXL") is intended to provide phototherapeutic light to the body. The MultiClearXL is generally indicated to treat dermatological conditions. The MultiClearXL's specific indication is for use in UVB phototherapy and PUVA photochemistry to treat psoriasis, vitiligo, atopic dermatitis, and leukoderma and for the use of visible blue/violet light to treat moderate inflammatory acne vulgaris.

## **Technological Characteristics**

The MultiClearXL is a computer controlled, high-intensity lamp intended for treatment of dermatological disorders by emitting a homogenous UV light dose in the UVB, UVA, and visible blue/violet light ranges. The desired dose of UVA or UVB or blue/violet light is selected using controls on the system front panel. The system consists of a console trolley, control console, illumination assembly, an extension arm (light guide and hand piece) and protective eyewear for the operator and patient.

## **Substantial Equivalence**

The MultiClearXL has the same intended use and indications and similar principles of operation and technological characteristics as a combination of the predicate devices. The MultiClearXL's specific indications

K041994 3/3

are specific indications for at least one of the predicate devices. Any minor differences between the MultiClearXL and its predicate devices raise no new issues of safety or effectiveness. Thus, the MultiClearXL is substantially equivalent to the predicate devices.



OCT 6 - 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

CureLight Ltd.  
c/o Mr. Jonathan S. Kahan  
Hogan & Hartson  
555 Thirteenth Street NW  
Washington, D.C. 20004

Re: K041994

Trade/Device Name: MultiClearXL Multiwavelength Targeted Phototherapy 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: July 23, 2004  
Received: July 23, 2004

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.

Page 2 - Mr. Jonathan S. Kahan

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" (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 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 Statement**

510(k) Number (if known): K041994

Device Name: MultiClearXL Multiwavelength Targeted Phototherapy System

Indications for Use:

The MultiClearXL Multiwavelength Targeted Phototherapy System ("MultiClearXL") is intended to provide phototherapeutic light to the body. The MultiClearXL is generally indicated to treat dermatological conditions. The MultiClearXL's specific indication is for use in UVB phototherapy and PUVA photochemistry to treat psoriasis, vitiligo, atopic dermatitis, and leukoderma and for the use of visible blue/violet light to treat moderate inflammatory acne vulgaris.

Prescription Use √  
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use       
(21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K041994