

K020591

1/2

MAY 16 2002

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness for the BClear™, Targeted PhotoClearing System, is submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(k) summary.

Applicant: Lumenis Inc.

Address: 1249 Quarry Lane, Suite 100
Pleasanton, CA 94566

Contact Person: C. Robert Payne, Jr., P.E.

Telephone: (925) 249-8031
Fax: (925) 249-8010

Preparation Date: February 27, 2002

Device Trade Name: BClear™

Common Name: Localized, narrow band ultraviolet phototherapy equipment

Classification Name: Ultraviolet lamp for dermatologic/skin disorders (see 21 CFR 878.4630).

Legally Marketed Predicate Devices:
PhotoMedex, the parent of AccuLase, Inc.,
XTRAC™ Excimer Laser Phototherapy System,
AL7000 (K011382; K992914, K003705);
Daavlin Co.,
Psorawand™ (Psoralite; K930856).

System Description:

The BClear, Targeted PhotoClearing System, is an ultraviolet light source and energy delivery system that provides targeted energy to the treatment site while avoiding exposure to non-affected tissue. The light source is contained within a protective console. The complete system also includes a handpiece connected to the console via an umbilical. Timing and dosing parameters and an interface to other system features are controlled from a display panel on the console. The delivery system allows UV-B light to pass through the handpiece to selectively treat skin and nail lesions without exposure to the healthy skin.

Intended Use of the Device:

The BClear, Targeted PhotoClearing System, is a medical ultraviolet light source and delivery device intended for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema) and seborrheic dermatitis. The BClear, Targeted PhotoClearing System, is intended for use on all skin types (I - VI).

Substantial Equivalence:

Currently published clinical data supports UVB treatment of atopic dermatitis (eczema) and seborrheic dermatitis. The intended use of the BClear, Targeted PhotoClearing System, is within the scope of the predicate devices.

The BClear, Targeted PhotoClearing System, is currently indicated for treatment of psoriasis and vitiligo in 510(k) K011197.

Performance Data:

None. The technological specifications of the BClear, Targeted PhotoClearing System, are the same or very similar to those of the claimed predicate devices. The BClear, Targeted PhotoClearing System, has the same indications for use for which the claimed predicates have been cleared. Therefore, performance data is not required.

Conclusion:

Based on the foregoing, the BClear, Targeted PhotoClearing System, is substantially equivalent to the legally marketed, claimed predicate devices for the purposes of this 510(k) submission.



MAY 16 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. C. Robert Payne, Jr., P.E.
Director of Regulatory Affairs/Quality Assurance
Lumenis, Inc.
1249 Quarry Lane, Suite 100
Pleasanton, CA 94566

Re: K020591
Trade/Device Name: BClear™
Regulation Number: 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: February 20, 2002
Received: February 22, 2002

Dear Mr. Payne:

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. C. Robert Payne, Jr., P.E.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,



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

INDICATION FOR USE STATEMENT

510(k) Number: K020591

Device Name: BClear™

Indications for Use:

The BClear™, Targeted PhotoClearing System, is a medical ultraviolet lamp and delivery device that is intended for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema) and seborrheic dermatitis. The BClear, Targeted PhotoClearing System, is intended for use on all skin types (I – VI).

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-the-Counter Use
(per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K 020591