MAY - 5 2005

510(K) Summary

K050080

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	January 12, 2005
Device Trade Name:	Excilite and Excilite μ
Common Name:	Narrow band ultraviolet phototherapy equipment
Classification Name:	Ultraviolet lamp for dermatology disorders. FTC 21 CFR 878.4630
Equivalent Device:	BClear phototherapy system
Device Description:	Excilite and Excilite-μ phototherapy systems have a XeCl excimer gas lamp located in the handpiece. It is a light source with a range approximately 306 - 310 nm wavelength. Emission activation is by finger switch. Overall weight of the laser is 19 Kg, and the size is 50x38x24 cm (HxWxD). Electrical requirement is 115 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	The Excilite and Excilite μ systems are indicated for the treatment of leukoderma, psoriasis, vitiligo, eczema, and seborrheic dermatitis.
Comparison:	The Excilite and Excilite μ systems have an identical indication for uses, the same principle of operation, and essentially the same wavelength range and pulse energy range as the predicate device.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Excilite and Excilite μ are both safe and effective devices for the treatment of leukoderma, psoriasis, vitiligo, eczema, and seborrheic dermatitis.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2005

Mr. George Cho
Senior Vice President
Cynosure Incorporated
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K050080
Trade/Device Name: Cynosure Excilite and Excilite μ
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: II
Product Code: FTC
Dated: March 23, 2005
Received: March 24, 2005

Dear Mr. Cho:

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 (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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050070

Device Name: Cynosure Excilite and Excilite μ

Indications For Use:

The Excilite and Excilite μ phototherapy systems are indicated for the treatment of leukoderma, psoriasis, vitiligo, eczema, and seborrheic dermatitis, for skin types I to VI.

Prescriptive Use X OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K050070

Prescription Use X OR Over-The-Counter Use