K041095

MAY 26 2004

510(K) Summary

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	April 26, 2004
Device Trade Name:	Photosilk and Photosilk Plus
Common Name:	Intense pulsed light system
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	Photolight PL system
Device Description:	Photosilk and Photosilk Plus are intense pulsed light systems, having a Xenon flashlamp located in the handpieces. It is a light source with a wavelength range of approximately 400 - 1200nm. Light emission activation is by foot switch. Overall weight of the laser is 65 Kg, and the size is 103x50x48 cm (HxWxD). Electrical requirement is 220 VAC, 15A, 50-60 Hz, single phase. Skin cooling is provided by the integrated cooling handpiece that contains cooled water circulated through the handpiece body, the face of which is in contact with the skin.
Intended Use:	The Photosilk and Photosilk Plus systems are indicated for permanent hair reduction, and the treatment of benign vascular and pigmented lesions.
Comparison:	The Photosilk and Photosilk Plus are substantially equivalent to the Photolight PL, with the same principle of operation, the same wavelength and essentially the same power range as the predicate device for the same indications for uses.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Photosilk and Photosilk Plus are another safe and effective device for permanent hair reduction, and treatment of benign vascular and pigmented lesions.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2004

Mr. George Cho
Senior Vice President of Medical Technology
Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K041095
Trade/Device Name: Photosilk and Photosilk Plus
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: April 26, 2004
Received: April 27, 2004

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.

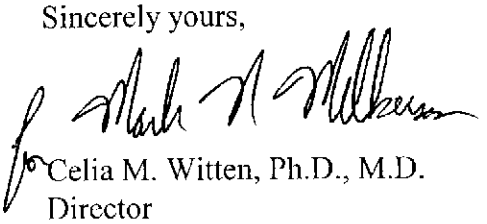
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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

510(k) Number (if known): K041095

Device Name: Photosilk and Photosilk Plus pulsed light system

Indications For Use:

The Photosilk and Photosilk Plus pulsed light system is indicated for permanent hair reduction. It is also indicated for photocoagulation of dermatological vascular lesions, photothermolysis of blood vessels (treatment of facial and leg veins), and the treatment of benign pigmented lesions.

The integrated cooling handpiece is intended to provide pre-cooling of the epidermis, to reduce thermal injury to the epidermis, and to reduce patient pain and discomfort associated with light applications.

Prescription Use ☑
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use_____
(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)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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