

FEB - 9 2004

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510(K) Summary

Submitter: Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, MA 01824

Contact: George Cho
Senior Vice President of Medical Technology

Date Summary Prepared: December 23, 2003

Device Trade Name: Cynosure Apogee Elite Laser

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.4810

Equivalent Device: Cynosure Apogee TKS, Cynosure Acclaim

Device Description: Cynosure Apogee Elite laser (755nm), having an Alexandrite crystal rod as the lasing medium, with a wavelength of 755 nm. The 1064 nm wavelength is generated from the Nd:YAG laser head.

Laser activation is by either finger or foot switch. Overall weight of the laser is 45 Kg, and the size is 113x53x84 cm (HxWxD).

Electrical requirement is 230 VAC, 50A, 50-60 Hz, single phase.

Intended Use: The Cynosure Apogee Elite laser is indicated for permanent hair reduction and the treatment of vascular lesions, pigmented lesions, and wrinkles.

Comparison: The Cynosure Apogee Elite laser is substantially equivalent to the predicate devices, with the same principle of operation, the same wavelength and essentially the same power range and the same indications for uses.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Cynosure Apogee Elite laser is another safe and effective device for permanent hair reduction and treatment of vascular lesions, pigmented lesions and wrinkles.

Additional Information: none



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K034030
Trade/Device Name: Cynosure Apogee Elite Laser
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: December 24, 2003
Received: December 29, 2003

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.

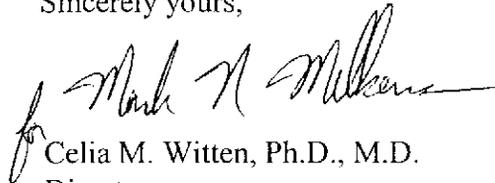
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish at the end.

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): K034030

Device Name: Cynosure Apogee Elite Dermatological Laser

Indications For Use:

755 nm:

The Cynosure Apogee Elite Dermatological Laser is indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime. It is used for all skin types (Fitzpatrick I - VI) including tanned skin.

It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

1064 nm:

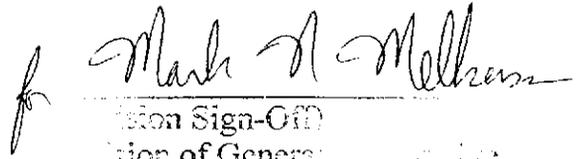
The Cynosure Apogee Elite Dermatological laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café' au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Region Sign-Off
Division of General
Center for...

K034030

Prescription Use

OR

Over-The-Counter-Use