

JUN - 4 2003

510(K) Summary

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

Contact: George Cho  
Senior Vice President of Medical Technology

Date Summary Prepared: May 9, 2003

Device Trade Name: Cynosure Apogee-TKS II Laser

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser  
79-GEX  
21 CFR 878.48

Equivalent Device: Cynosure Apogee-TKS

Device Description: Cynosure Apogee-TKS II laser, having an Alexandrite crystal rod as the lasing medium. It is a laser with a wavelength of 755nm.  
  
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-TKS II laser is indicated for permanent hair reduction and the treatment of vascular lesions, pigmented lesions and wrinkles.

Comparison: The Cynosure Apogee-TKS II 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-TKS II laser is another safe and effective device for permanent hair reduction and treatment of vascular lesions, pigmented lesions and wrinkles.

Additional Information: none



JUN - 4 2003

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: K031488  
Trade/Device Name: Cynosure Apogee-TKS II 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: May 9, 2003  
Received: May 13, 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.

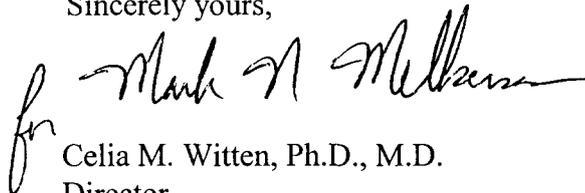
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Mr. George Cho

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. 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) you may obtain. 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 Mark A. Melanson

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): K031488

Device Name: Cynosure Apogee-TKS II Dermatological Laser

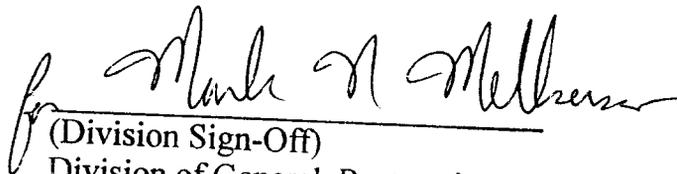
Indications For Use:

The Cynosure Apogee-TKS II 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K031488

Prescription Use

OR

Over-The-Counter Use