

JUN 29 2000

k992757

## 501(K) summary

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

Contact: George Cho  
Senior Vice President, Medical Technology

Date Summary Prepared: August 12, 1999

Device Trade Name: Apogee-TKS Laser

Common Name: Medical Laser System

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

Equivalent Device: Cynosure Apogee Laser

Device Description: The Apogee-TKS Laser consists of three interconnected sections: the power supply, the water cooling and heating system and the optical bench. The device is capable of delivering 60 J/cm<sup>2</sup> at 5, 10, 20 or 40 milliseconds pulse width.

Intended Use: For stable, long-term, or permanent hair reduction.

Comparison: The Apogee-TKS Laser is substantially equivalent to the Cynosure Apogee Laser in terms of treatment wavelength, pulse duration, pulse energy and biological effects.

Non-clinical Performance Data: None

Clinical Performance Data: None

Conclusion: The Apogee-TKS Laser is another safe and effective way for permanent hair reduction.

Additional Information: None requested at this time.



**JUN 29 2000**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K992757  
Trade Name: Cynosure Apogee-TKS Dermatological Laser  
Regulatory Class: II  
Product Code: GEX  
Dated: May 25, 2000  
Received: May 26, 2000

Dear Mr. Cho:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

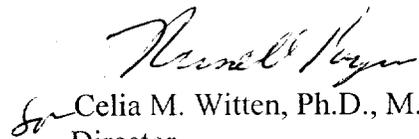
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. George Cho

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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): K992757

Device Name:

Cynosure Apogee-TKS Dermatological Laser for Permanent Hair Epilation

Indication for Use:

The Cynosure Apogee-TKS laser is indicated for vascular lesion removal and stable, long-term, or permanent hair reduction.

Permanent hair reduction is defined as long-term, stable reduction in the number of hairs re-growing after a treatment regime. The number of hairs re-growing must be stable over a time greater than the duration of the complete growth cycle of hair follicles, which varies from 4-12 months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treated area.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K992757

Prescription Use X  
(Per21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_