APR 3 0 2004

K 040289

510(K) Summary

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	February 5, 2004
Device Trade Name:	SmartLite D Laser
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	Fisma Elite Family of Lasers, frequency doubled Nd:YAG Fisma Dental 200, Dental 300, Dental 400
Device Description:	SmartLite D is a frequency doubled Nd:YAG laser, having a Nd:YAG crystal rod as the lasing medium. It is a laser with a wavelength of 532 nm. Laser activation is by footswitch. Overall weight of the laser is 10 Kg, and the size is 27x26x36 cm (HxWxD). Electrical requirement is 230 VAC, 15A, 50-60 Hz, single phase.
Intended Use:	The SmartLite D is indicated for ablation, incision, excision, coagulation and vaporization of tissue in ophthalmology, dermatology, ENT & dentistry.
Comparison:	The SmartLite D laser has an equivalent indication for uses, the same principle of operation, the same wavelength and essentially the same pulse energy range as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The SmartLite D laser is another safe and effective device for the intended uses.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2004

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

Re: K040289
Trade/Device Name: SmartLite D 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: February 5, 2004
Received: February 6, 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.

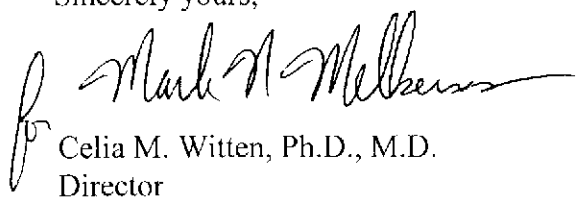
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K040289

Device Name: SmartLite D Laser

Indications For Use: The SmartLite D laser device is intended for ablation, incision, excision, vaporization and coagulation of soft tissue, in ophthalmology, ENT, and dermatology. In addition, the laser is intended for application in dentistry including:

- Frenectomy
- Treatment of Oral Mucous Cysts
- Treatment of Benign Vascular Lesions
- Photocoagulation of Superficial Vessels
- Vaporization of Superficial Blood Vessels or Lymphs Containing Vessels
- Treatment of Superficial Tongue Lesions
- Tissue Management and Hemostasis for Crown and Bridge Impressions
- Incision and Drainage for Abscess
- Gingivoplasty / Gingivectomy
- Hemostasis during Dental Procedures
- Operculectomy (Operculotomy)
- Excisional Biopsy
- Free Gingival Graft (Adjunct)
- Vestibuloplasty
- Soft Gutta Percha
- Treatment of Canker sores, Herpetic Lesions, and Aphthous Ulcers
- Laser-assisted Bleaching / Whitening of the Teeth

Prescription Use ✓ 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)

for Mark N Milhoan

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

510(k) Number K040289