MAR 1 7 2009

510(K) Summary

K090235

Submitter:	Cynosure, Inc., 5 Carlisle Road, Westford, MA 01886
Contact:	George Cho, Senior Vice President of Medical Technology
Date Summary Prepared:	January 30, 2009
Device Trade Name:	Cynosure Elite MPX Laser System with XPL Handpiece
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.4810
Equivalent Device:	Cynosure Apogee Elite (K034030) and Cynosure PhotoSilk Plus Pulsed Light System (K051442)
Device Description:	The Cynosure Elite MPX Laser System with XPL Handpiec is a solid state laser system. It emits laser energy at 755nm and 1064nm wavelengths. It also incorporates a pulsed light XPL handpiece. Laser activation is by footswitch. Electrical requirement is 230 VAC, 30A, 50-60 Hz, single phase.
Intended Use:	Elite MPX 755 nm: The Elite MPX Laser system 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 – IV) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. Elite MPX 1064 nm: The Elite MPX laser system 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 lakes, 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, verrucea, 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 the hair follicles, and for the treatment of pseudofolliclitis (PFB). XPL Handpiece: The XPL Pulsed Light handpiece is intended for permanent hair reduction and the treatment of dermatological vascular lesions, facial and leg veins, benign pigmented lesions, and inflammatory acne.

Comparison:	The Cynosure Elite MPX Laser System with XPL Handpiec has the same indications for use, the same principle of operation, and same parameters as the predicate device(s).
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Elite MPX Laser System with XPL Handpiece is a safe and effective device for the indications specified.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Cynosure, Inc.
% Mr. George Cho
Sr. Vice President
5 Carlisle Road
Westford, Massachusetts 01886

Re: K090235
Trade/Device Name: cynosure Elite MPX Laser System with XPL Handpiece
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: January 30, 2009
Received: February 2, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090235

Device Name: Cynosure Elite MPX Laser System with XPL Handpiece

Indications For Use:

Elite MPX 755 nm:
The Elite MPX Laser system 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 – IV) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

Elite MPX 1064 nm:

The Elite MPX laser system 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 lakes, 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, verrucea, 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 the hair follicles, and for the treatment of pseudofolliclitis (PFB).

XPL Handpiece:

The XPL Pulsed Light handpiece is intended for permanent hair reduction and the treatment of dermatological vascular lesions, facial and leg veins, benign pigmented lesions, and inflammatory acne.

Prescriptive Use X 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)

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

510(k) Number K090235