K051922

SEP 14 2005

510(K) Summary

Submitter:	Cynosure Inc 5 Carlisle Road Westford, MA 01886
Contact:	George Cho Senior Vice President
Date Summary Prepared:	July 14, 2005
Device Trade Name:	'MLS Family' Diode Laser – MLS Mix5, MLS M1, MLS M6
Common Name:	Diode Laser
Classification Name:	Infrared Lamp 21 CFR 890.5500
Equivalent Device:	MLT-1000 IR Laser System
Device Description:	The 'MLS Family' Diode Laser provides 808 and 905 nm wavelengths. Laser emission activation is by user selectable controller. Electrical requirement is 230 VAC, 20A, 50-60 Hz, single phase.
Intended Use:	The 'MLS Family' Diode Laser is intended to provide topical heating for the purpose of elevating tissue temperature for temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.
Comparison:	The 'MLS Family' Diode Laser has the same indications for use, the same principle of operation, and similar performance specifications as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The 'MLS Family' Diode Laser 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

SEP 14 2005

Mr. George Cho
Senior Vice President
Medical Technology
Cynosure, Inc.
5 Carlisle Road
Westford, Massachusetts 01886

Re: K051922
Trade/Device Name: MLS Family Diode Laser-MLS Mix5, MLS M1, MLS M6
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: August 25, 2005
Received: August 26, 2005

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 (240) 276-0115. 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,

Barbara Buehrd

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

Enclosure

510(k) Number (if known): K051922

Device Name: 'MLS Family' Diode Laser – MLS Mix5, MLS M1, MLS M6

Indications For Use:

The 'MLS Family' Diode Laser is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of muscle and joint pain and stiffness, arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

Prescriptive Use X (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use ______ (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)

[signature] for MXM

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

510(k) Number K051922