K111901

NOV - 9 2011

510(K) Summary

Submitter:	ASA srl Via Volta, 9 36057 ARCUGNANO (VI) ITALY
Contact:	Lucio Zaghetto, President ASA srl c/o Cynosure, Inc. 5 Carlisle Road Westford, MA 01886
Date Summary Prepared	June 30, 2011
Device Trade Name	ASA 'Mphi Family' Diode Laser
Common Name	Infrared Lamp 21 CFR 890.5500
Equivalent Devices:	ASA 'M Family' Diode Laser
Device Description	The ASA 'Mphi Family' Diode Lasers provides 808 and 905 nm wavelengths. Laser emission activation is by the user selectable controller. Electrical requirement is 110-250VAC, 50VA, 50-60Hz, single phase or battery mode.
Intended Use	The ASA 'Mphi Family' Diode Lasers 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 ASA 'Mphi Family' Diode Lasers has the same indications for use , the same principle of operation, and identical performance specifications as the predicate devices.
Nonclinical Performance Data:	none
Clinical Performance Data	none
Conclusion	The ASA 'Mphi Family' Diode Lasers 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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ASA srl
% Cynosure, Inc.
Mr. Anthony Burns
Director of Regulatory Affairs
5 Carlisle Road
Westford, Massachusetts 01886

Re: K111901
Trade/Device Name: ASA 'Mphi Family' Diode Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: October 11, 2011
Received: October 13, 2011

Dear Mr. Burns:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

510(k) Numer (if know): K111901

Device Name: ASA 'Mphi Family' Diode Laser

Indication For Use:

The ASA 'Mphi 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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111981