510(k) Summary of Saftey and Effectiveness

1. Submitter's Name and Address

American Spine Center, Ltd.
100 Mascoutah Avenue
Belleville, IL 62220-3801
Phone: 618-233-6824
Fax: 618-233-6825

Key Contact: James J. White, President

Date Prepared: 09/22/2005

2. Device Name

Proprietary Name: Clini-Lase Laser System
Common / Usual Name: Infrared Lamp
Classification Name: Infrared Lamp (21 CFR 890.5500)
Product Code: ILY

Model #: CL-Base, CL-2000, CL-1200, CL-500, CL-300, CL-275, CL-155, CL-55, CLP-Base, CLP-275 and CLP-55.

3. Legally-Marketed Predicate Devices

The Clini-Lase System are substantially equivalent to other infrared sources (product code ILY) currently in commercial distribution such as:

K032231 MedX LCT100 & MedX LCS Portable Laser
K033923 Thor DDII IR Lamp Systems
K040662 Vectra Genisis Laser System
K043586 Laser Sys*Stim 540, Model ME 540
K050370 Palomar LuxIR Handpiece

Description of the Device

The Clini-Lase System consists of a clinical and portable control base unit, and seperate attachment infrared heat lamp probes. The control base unit houses the electronics, LCD display and system controls and is powered by 12 Volts DC suplied by an AC-DC Power Adapter. The attachment probes produce infrared radiation to provide topical heating. Various single and cluster probes are available for the base units. The probes are conected by a readily replacable independent cable assembly.

510(k) Premarket Notification for the Clini-Lase System

4. Intended Use of the Device

The Clini-Lase System is an infrared lamp that is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperture for the temporary relief of minor muscle and joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the Clini-Lase System may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

5. Performance Data

The differences in the specifications of the Clini-Lase System and the predicate devices do not result in different performance or raise new questions of safety or efficacy.

6. Non-clinical Data

Potentail hazards are identified and have been mitigated by design and labeling.

7. Conclusion

Based on the foregoing, the Clini-Lase System is substantially equivalent to the legally-marketed predicate devices.

Name of Manufacturer: American Spine Center, LTD.
Laser Model Name and Number: Clini-Lase System CL-2000, CL-1200, CL-155, CL-500, CL-300, CL-275, CL-55

Laser Type: (Circle all that apply)
Alexandrite, Argon, CO2, Copper-Vapor, Diode, Dye, Nd:YAG, Erbium, Hol: YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other
LED's

Indications in this application: The Clini-Lase System is an infrared lamp that is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain associated with arthritis, for the temporary increase in local circulation where applied, and the relaxation of muscles, minor sprains and strains, and minor muscular back pain.

FDA Document Control Number: K052647

FDA Product Code: 79GEX

Reviewer Computer Initials: CYH

Date of Clearance Letter: 11/04/05

Basis of Approval: (Circle all that apply)
Predicate Device (PD), Clinical Data (CD), Animal Data (AD), Specifications (SPECS), Bench Test Data (BTD), Historical Information (HI), Other _____

Description of Laser:
Operation Modes: (Circle all that apply)
CW, Pulsed, Q-Switched, Mode Locked, Contact, Free Beam, Other _____

Wavelength in Nanometers: 808, 650, 785

Power/Energy Range (Watts/Joules): 25 mW – 500 mW

Pulse Width: n/a

Repitition Rate: n/a

Delivery System: hand held probes
Comments:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 2005

James J. White
President
American Spine Center, LTD.
Clini-Lase
100 Mascoutah Avenue
Belleville, Illinois 62220-3801

Re: K052647
Trade/Device Name: Clini-Lase Systems, with Models: CL-Base, CL-2000, CL-1200, CL-500, CL-300, CL-275, CL-155, and CL-55
CLP-Base, CLP-275 and CLP-55
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: October 31, 2005
Received: October 31, 2005

Dear Mr. White:

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/industry/support/index.html

Sincerely yours,

for

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

Enclosure

K052647/S

510(k) Premarket Notification for the Clini-Lase System

Indication for Use:

K052647

510(k) Number (if known): _____

Device Name: Clini-Lase System, with Models:

CL-Base, CL-2000, CL-1200, CL-500, CL-300, CL-275, CL-155, and CL-55.

CLP-Base, CLP-275 and CLP-55.

Indication For Use:

The Clini-Lase System is an infrared lamp that is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperture for the temporary relief of minor muscle and joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, the Clini-Lase System may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

X

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-the Counter Use _____ (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 K052647