NOV 2 0 2003

K032787 1 of 2

Section 6. 510(K) Pre-Market Notification Summary of Safety and Effectiveness

1. Submitter's Name and Address

Spectrum Laser & Technologies, Inc.
4980A Centennial Blvd.
Colorado Springs, CO 80919
Phone: (719) 264-7632
Fax: (719) 548-8289

Key Contact: Thomas R. Radebaugh

Date Prepared: 8/26/2003

2. Device Name

Proprietary Name: Neurolase™ Series
Common / Usual Name: Infrared Lamp
Classification Name: Infrared Lamp (21 CFR 890.5500)
Product Code: ILY

3. Legally-Marketed Predicate Devices

The Neurolase™ devices are substantially equivalent to other infrared sources currently in commercial distribution such as the Super Nova/Acubeam systems (K001179) manufactured by Light ForceTherapy, Inc., the Medx 1000 Series devices (K020017) manufactured by Medx Health Corporation, the Photonic Stimulator (K974468) manufactured by Bales Scientific, the SLP 1000 Thermapulse (K024179) manufactured by Palomar, the Pain-X 2000 (K982546) manufactured by Diomedics, and the SLP 1000 Thermapulse (K024179) manufactured by Palomar.

4. Intended Use of the Device

The Neurolase™ devices emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature to provide temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm. These devices may temporarily increase blood circulation, and may be used to promote relaxation of muscle tissue.

5. Description of the Device

The Neurolase™ devices consist of a control unit and a handpiece The control unit houses the power supply, control electronics, calibration port, and infrared radiation source. The source is coupled to a fiber optic cable that delivers the energy to the patient through the handpiece.

6. Performance Data

The differences in the specifications of the Neurolase™ devices and the predicate devices result in enhanced performance for the Neurolase™ devices and do not raise new questions of safety or efficacy.

7. Testing

Prototype units have undergone preliminary testing to ensure compliance with UL2601 and FCC Part 15 requirements. Once marketing clearance is granted, safety and emissions testing will take place at a registered body. Production units will each be run through an Acceptance Test Procedure to ensure compliance with the System Specification. All components have been chosen to ensure compliance with the aforementioned standards.

8. Conclusion

Based on the foregoing, the Neurolase™ Series is substantially equivalent to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

Mr. Thomas R. Radebaugh
Vice President of Engineering
Spectrum Laser & Technologies, Inc.
4980A Centennial Boulevard
Colorado Springs, Colorado 80919

Re: K032787
Trade/Device Name: Neurolase™ Series
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: September 2, 2003
Received: September 9, 2003

Dear Mr. Radebaugh:

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,

Miriam C. Provost

for 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

Section 4. Statement of Indications for Use

Indication for Use

510(k) Number: K032787

Device Name: Neurolase™ Series

Indications for Use:

The Neurolase™ devices are an infrared lamp per 21 CFR 890.5500 that emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature to provide temporary relief of minor muscles and joint pain and stiffness, minor pain and stiffness associated with arthritis, or muscle spasm. These devices may temporarily increase blood circulation, and may be used to promote relaxation of muscle tissue.

Miriam C. Provost

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

510(k) Number K032787