



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Phoenix Thera-Lase Systems, LLC  
% Ms. Diane Rutherford  
Ken Block Consulting  
1201 Richardson Drive, Suite 280  
Richardson, Texas 75080

September 4, 2015

Re: K151521

Trade/Device Name: Phoenix Thera-Lase System Model 3000  
Regulation Number: 21 CFR 890.5550  
Regulation Name: Infrared lamp  
Regulatory Class: Class II  
Product Code: ILY  
Dated: August 5, 2015  
Received: August 7, 2015

Dear Ms. Rutherford:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**Joshua C. Nipper -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)

K151521

Device Name

Phoenix Thera-Lase System Model 3000

Indications for Use (Describe)

The Phoenix Thera-Lase System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 5. 510(k) SUMMARY

Submitter: Phoenix Thera-Lase Systems, LLC  
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Dallas, Texas 75231

Contact Person: Mr. Gary Bellinger  
Managing Partner  
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Date Prepared: May 27, 2014

Trade Name: Phoenix Thera-Lase System

Common Name: Infrared heat lamp

Classification: ILY 890.5500 Class 2 Lamp, Infrared, Therapeutic Heating

Predicate Device: K120604 K-Laser ELTECH s.r.l.  
K101893 Nexus Laser USA Laser Biotech Inc  
K122125 ASA Laser El.En. S.p.A  
K121363 Diowave Laser Technological Medical Advancements, Inc

Device Description: The Phoenix Thera-Lase System is a stand-alone, solid-state class IV laser system specifically designed to provide efficient, high-power laser output with air-cooling and an output wavelength of 1060 nm. The laser output provides a 0.75-1.88 inch diameter spot to provide non-contact laser output to patients. The laser system has three different operation modes: Continuous wave, Single, and Repeat mode.

The Laser system consists of three main components: Laser Diode Module, Remote Controller, and Fiber Optic delivery cable with hand piece. The Laser Diode Module contains the power supply system and the laser diode. The Remote Controller controls the laser module through a touch screen activated control panel. The Fiber Optic delivery cable is connected to the Laser Diode Module to provide a route for administration of the laser output.

Statement of Intended Use / Indications for Use: The Phoenix Thera-Lase System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with minor arthritis, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation.



Summary of  
Technological  
Characteristics:

The Phoenix Thera-Lase System is a portable, software controlled, non-contact laser device. The laser system emits energy in the infrared spectrum with output power of 35 watts and output wavelength of 1064 nm. The laser system consists of Gallium-Aluminum-Arsenide (GaAlAs) single diode and can be operated on three different operation modes; Continuous Wave, Single and Repeat mode. Operations are controlled using an LCD touch panel to set laser output specifications. Options (e.g. mode, timer, power level, etc) can be set to provide desired parameters.

Safety features are provided with the Laser system to ensure patient and user safety. These features include automatic overload and no-load trip, automatic shut off, an emergency stop button, regulated power output, and interlock functions.

Summary of  
Non-Clinical Data:  
Test Data:

Testing was performed which demonstrates that the device is safe and effective, performs comparably to the predicate device(s), and is substantially equivalent to the predicate device(s). Tests included verification/validation testing to internal functional specifications (including software), and non-clinical skin temperature evaluations. Documentation was provided demonstrating compliance of the Phoenix Thera-Lase System to all FDA requirements stated in *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards.

In addition, the Phoenix Thera-Lase System was subjected to independent laboratory testing for both electrical safety and electromagnetic compatibility (EMC). Test results demonstrate that the device complies with all applicable requirements for medical device electrical safety and EMC, including the following:

- FDA recognized medical device electrical safety consensus standard AAMI / ANSI ES60601-1:2005/(R)2012 And C1:2009/(R)2012 And, A2:2010/(R)2012 *Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance*, and
- FDA recognized medical device EMC consensus standard IEC 60601-1-2 Edition 3: 2007-03 *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*.

In accordance with the FDA guidance document *Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Device*, the temperature range at the skin surface where the device is applied has been evaluated and the results included within this submission.

These verification/validation activities successfully demonstrate that the



Phoenix Thera-Lase System correctly performs as designed, has been validated for its intended use, and raises no new questions regarding either safety or effectiveness when compared to the predicate device(s). Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the Phoenix Thera-Lase System.

Conclusion:

Phoenix Thera-Lase Systems, LLC considers the Phoenix Thera-Lase System to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.