MAR 19 2004

## 510(k) SUMMARY—Acculaser™ Pro4

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| **Submitter Name:** | **PhotoThera, Incorporated** |
| **Submitter Address:** | 2260 Rutherford Rd.<br>Suite 101<br>Carlsbad, CA 92008 |
| **Contact Person:** | Jackson Streeter, M.D.<br>Chief Executive Officer |
| **Phone Number:** | 760-496-3700 |
| **Fax Number:** | 760-496-3707 |
| **Email:** | jstreeter@photothera.com |
| **Date Prepared:** | September 13, 2002 |
| **Device Trade Name:** | **Acculaser™ Pro 4** |
| **Device Common Name:** | Low level laser therapy device |
| **Classification Name:** | Lamp, Non-heating, for Adjunctive Use in Pain Therapy<br>21 CFR 890.550; NHN |
| **Predicate Devices:** | K020657, Acculaser, Inc., Acculaser™ Pro LLLT<br>K010175, MicroLight Corp., MicroLight 830™ Laser System<br>K012580, TUCO Innovations, Inc., TUCO Erchonia PL2000 |
| **Device Description:** | The Acculaser™ Pro4 is a low level laser therapy device. It is non-thermal and emits infrared energy at 830 nm. |
| **Intended Use:** | The Acculaser™ Pro4 is indicated for adjunctive use in providing temporary relief of pain associated with iliotibial band syndrome. |

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| **Performance Testing:** | Bench test and clinical performance data demonstrate that the Acculaser™ Pro4 low level laser therapy device is safe and effective in providing adjunctive therapy for the temporary relief of pain and disability associated with ITBS. |
| **Conclusion:** | Based on the same intended use and similarity in design and technological characteristics, the Acculaser™ Pro4 is substantially equivalent to the predicate devices. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2004

PhotoThera, Inc.
c/o Ms. Patsy Trisler
Regulatory Consultant
5610 Wisconsin Avenue, Suite 304
Chevy Chase, Maryland 20815

Re: K023060
Trade/Device Name: Acculaser™ Pro 4
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, non-heating, for adjunctive use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: December 22, 2004
Received: December 22, 2004

Dear Ms. Trisler:

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,

for Miriam C Provost

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

**510(k) Number (if known):** K023060

**Device Name:** Acculaser™ Pro4

**Indications for Use:**

The Acculaser™ Pro4 is indicated for adjunctive use in providing temporary relief of pain associated with iliotibial band syndrome.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-The-Counter Use

Miriam C. Provost

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

**510(k) Number** K023060

(Optional Format 1-2-96)