K083822

## 510(k) SUMMARY— LaserTouchOne™

MAY - 6 2009

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| Submitter Name: | Laser Health Technologies, LLC |
| Submitter Address: | 10234 North 58th Place<br>Paradise Valley, AZ 85253 |
| Contact Person: | James Mantle, Manager |
| Phone Number: | 602-821-1659 |
| Date Prepared: | April 21, 2009 |
| Device Trade Name: | LaserTouchOne™ |
| Device Common Name: | Low level (cold) laser device (LLLT) and transcutaneous electrical nerve stimulator (TENS) for pain therapy |
| Classification Numbers: | 21 CFR 890.5500; 21 CFR 882.5890 |
| Classification Names: | Non-heating lamp, for adjunctive use in pain therapy;<br>Transcutaneous electrical nerve stimulator |
| Product Codes: | NHN; GZJ |
| Predicate Devices: | Rebco Trading Co., Pro Med 100 (K822854)<br>Stargate International, Inc., Quantum Light Therapy System (K032816)<br>Xanacare Technologies, Inc., ComboCare 2000 (K081141)<br>Biomedical Design Instrumments, Electro-Acuscope 85 (K883911) |
| Statement of Intended Use: | The LaserTouchOne™ is a low level laser and electrical stimulation device. This combination of low level light and electrical stimulation provides symptomatic relief of chronic, intractable pain, and is indicated for adjunctive treatment of post-surgical and post-traumatic acute pain and for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin. |

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| Device Description: | The LaserTouchOne™ device is a rechargeable hand-held pain therapy device. It combines the technology of low level laser and transcutaneous electrical nerve stimulation in one unit. The low level (cold) laser therapy is delivered with a single diode laser of <1 mW, 670 nm, and the pulsed electrical stimulation is of low magnitude. The device is provided with a power recharging unit and a tube of electroconductive gel. |
| Comparison to the Predicate Devices: | This device, with respect to performance in a clinical trial in which it was compared to one of the TENS predicate devices and to the low level light predicate device, its intended use, and the device characteristics, is substantially equivalent to the technologies provided by the predicate devices. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

Laser Health Technologies, LLC.
% Ms. Patsy Trisler
5600 Wisconsin Avenue Suite 509
Chevy Chase, Maryland 20815

Re: K083822
Trade/Device Name: LaserTouchOne ™
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ, NHN
Dated: April 21, 2009
Received: April 21, 2009

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for David Krone

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

Enclosure

**510(k) Number (if known):** K083822

**Device Name:** LaserTouchOne™

**Indications for Use:**

The LaserTouchOne™ is a low level laser and electrical stimulation device. This combination of low level light and electrical stimulation provides symptomatic relief of chronic, intractable pain, and is indicated for adjunctive treatment of post-surgical and post-traumatic acute pain and for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

Prescription Use ___X___ (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 OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*(Posted November 13, 2003)*

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

510(k) Number K083822