K100116

510(k) SUMMARY— LaserTouchOne™(OTC)

APR 15 2010

Submitter Name:	Laser Health Technologies, LLC
Submitter Address:	10234 North 58th Place Paradise Valley, AZ 85253
Contact Person:	James Mantle, Manager
Phone Number:	602-821-1659
Date Prepared:	January 12, 2010
Device Trade Name:	LaserTouchOne™(OTC)
Device Common Name:	Low level (cold) laser device and transcutaneous electrical nerve stimulator for pain therapy
Classification Numbers:	21 CFR 890.5500; 21 CFR 882.5890
Classification Names:	Non-heating lamp, for adjunctive use in pain therapy; Transcutaneous electrical nerve stimulator, over-the-counter
Product Codes:	NHN; NUH
Predicate Devices:	K083822, LaserTouchOne™; Laser Health Technologies, LLC K080513; QLaser System; 2035, Inc. K063743; Rhythm Touch Q 2-Way, Shockim Enterprise Ltd.
Statement of Intended Use:	The LaserTouchOne™(OTC) 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.
Device Description:	The LaserTouchOne™ (LTO) 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 (LLLT) is delivered with a single diode laser of <1 mW, 670 nm. The pulsed electrical stimulation is simultaneously delivered though stainless steel contact points, using an electroconductive gel as the contact medium.

Comparison to the Predicate Devices:	This device is identical to the LTO device cleared on May 6, 2009 by FDA for prescription use. The prior 510(k) contained data from a randomized, controlled clinical trial in which the LTO performed favorably compared to predicate TENS and LLLT devices. This 510(k) contains data from a second study, conducted at a clinical research site, which demonstrated the usability of the LTO-OTC device for over-the-counter use. The LTO-OTC, with respect to device characteristics is identical to the LTO predicate device, and with respect to technological characteristics and over-the-counter intended uses is substantially equivalent to the LLLT and TENS predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Laser Health Technologies
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Ms. Patsy J. Trisler
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5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

APR 1 5 2010

Re: K100116
Trade/Device Name: LaserTouchOne™ (OTC)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH, NHN
Dated: January 12, 2010
Received: January 15, 2010

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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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): _____

Device Name: LaserTouchOne™(OTC)

Indications for Use:

The LaserTouchOne™(OTC) 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 _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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 K100116