510(K) SUMMARY K082686 Page 1 of 2

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR ? 07.92

MAY 11 2009

1. **Submitter's Name:** **United Integrated Services Co., Ltd.**

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Contact: Mr. David O. Chang / Vice President

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Prepare Date : Feb.24,2009

2. **Device Name:**

Trade Name: Multi-Channel Laser Therapy System, **Model no.: LA-400**

Common Name: Laser Therapy

Classification name lamp, infrared, therapeutic heating

3. **DEVICE CLASS** The Multi-Channel Laser Therapy System, **(Model no.: LA-400)** has been classified as
Regulatory Class: II
Product Code: ILY
Regulation Number: 21CFR 890.5550

4. **Predicate Device:** The predicate device is the **ACUMED LASER, MODEL 1000 (K060153)** marketed by **LASER THERA, LLC..**

5. **Intended Use:** The **Multi-Channel Laser Therapy System (Model no.: LA-400)** is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and the joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.

6. **Device Description:** The Multi-Channel Laser Therapy System LA-400 is a non-invasive, portable therapeutic medical laser designed to deliver light energy to the target tissue. It is intended to emit energy in the infrared spectrum for the purpose of temporary relief of minor muscle and the joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.

LA-400 is the low level laser of two wave bands. One is 660nm (red light, visibility) and the other is 808nm (infrared light, invisibility).

LA-400 contains four (4) channels of laser. For each channel of the Multi-Channel Laser Therapy System , LA-400 makes use of cup + laser diode assembly hand-held to deliver the light energy to the designated treatment areas. The cup + laser diode assembly are put on the skin for treatment.

Note A : Basic operation and treatment of LA-400 is utilizing the laser module mounted in the cup (we call laser module cup) which will be hand-held and put on skin easily.

7. Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ISO 13485, IEC 60825-1, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **Multi-Channel Laser Therapy System (Model no.: LA-400)** has the same intended use and similar technological characteristics as the **ACUMED LASER, MODEL 1000 (K060153)** marketed by **LASER THERA, LLC.**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Multi-Channel Laser Therapy System (Model no.: LA-400)** 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

MAY 11 2009

United Integrated Services Co., Ltd.
% Mr. David O. Chang
Vice President
3F, No. 4, Lane 7, Pao-Kao Road
Hsintien City, Taipei Hsien
Taiwan, 23144

Re: K082686
Trade/Device Name: Multi-Channel Laser Therapy System
Model no.: LA-400
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: April 28, 2009
Received: April 29, 2009

Dear Mr. Chang:

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 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) 276-0115. 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K082686

Device Name: Multi-Channel Laser Therapy System
Model no.: LA-400
United Integrated Services Co., Ltd.

Indications For Use:

The Multi-Channel Laser Therapy System (Model no.: LA-400) is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and the joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082686