JUL 18 2008

510(K) SUMMARY

K080465

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name:	**WS FAR IR MEDICAL TECHNOLOGY CO., LTD.**
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Phone:	+886-2-8219-2005
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Contact:	**Miss Ruth Pui / Overseas sales Administrator**
2. Device Name :	
Trade Name:	WS™ THERAPY UNIT, Model # TY-101 series
Common Name:	Infrared Heating Lamp
Classification name	Lamp, Infrared
3. DEVICE CLASS	WS™ THERAPY UNIT (Model # TY-101 series) have been classified as Regulatory Class: II Product Code: ILY Panel : Physical Medicine Regulation Number: 21CFR 890.5500
4. Predicate Device:	The predicate device is the • **TDP CQ-27 Heat Lamp (K003538)** marketed by **Lhasa OMS, Inc.**.
5. Device Description:	The **WS™ THERAPY UNIT (Model # TY-101 series)**, is an infrared heating system which emits topical heat to the human body for therapeutic applications. It consists of an IR emitter (Emission spectrum ranges from 3 ~ 25 microns.), a control box, a supporting arm to allow for adjustment of the emitter locations, and a protection net on the emitter to prevent fire or direct touch by the user. The entire unit is mounted on base that is easy to move. The device uses 110 Vac as power source . it meets the related requirement of IEC 60601-1 Electrical Safety.

6. Intended Use: The WS™ THERAPY UNITS, TY-101N and TY-101F, may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of **minor** joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

7. Performance Summary: The device conforms to applicable standards includes IEC 60601-1, IEC 60601-1-2 & related standards----etc.

8. Conclusions:

The **WS™ THERAPY UNIT (Model # TY-101 series)** has the same intended use and similar technological characteristics as the **TDP CQ-27 Heat Lamp (K003538)** marketed by **Lhasa OMS, Inc.**. 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 **WS™ THERAPY UNIT (Model # TY-101 series)** 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

WS Far IR Medical Technology Corporation
% Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corporation
2904 N Boldt Drive
Flagstaff, Arizona 86001

JUL 18 2008

Re: K080465
Trade Name: WS Far Infrared Therapy Unit, Model # TY-101 Series
Regulation Number: 21 CFR 890.5500
~~Regulation Name: Infrared Lamp~~
Regulatory Class: Class II
Product Code: ILY
Dated: May 27, 2008
Received: May 27, 2008

Dear Ms. Reich:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): **K#080465**

Device Name: WS™ THERAPY UNIT,
Model # TY-101 series
WS Far IR Medical Technology Co., Ltd.

Indications for Use:

The WS™ THERAPY UNITS, TY-101N and TY-101F, may be used for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of **minor** joint pain associated with arthritis, the temporary increase in local circulation where applied, and relaxation of muscles. In addition, the lamp may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

Prescription Use _____ AND/OR Over-The-Counter Use V
(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 General, Restorative,
and Neurological Devices

510(k) Number K080465