DEC - 3 2003

K024027

510(k) Summary
Infrared Lamp, Models LW10D and LW30D

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Douglas Greene, Chairman

Prepared 11/25/02 by:
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Device: LightWave™ Infrared Photon Stimulator, Models, LW10D and LW30D

Common Name: Infrared Lamp

Classification: 890.5500, 89 ILY, Class II

SE Predicates:

a) C&H International
K020851, Infrared Heating Lamp
TDP Heat Lamp

b) BioScan, Inc.
K993684, Infrared Lamp
Spinal Pad

Device Description:

The devices are a family (models) of infrared lamps having the same indication for use and equivalent technology. The units are electrical and mechanical designs for use and convenience of users to provide topical heating. Heat is generated by LEDs (light emitting diodes) at 940 nm wavelength. .

SkyTech Infrared Photon Stimulator Model Differentiation

Model	Number of LEDs	Output Power	Wavelength	Power Source	Light Pattern	Treatment Area	Battery Life	Recommended Treatment
LW10D	9	20 mW	940 nm	9V DC battery or 110V AC/9V DC adapter	145 Hz pulse	~225 square mm	6 hours continuous, 30 hours pulsing	15 minutes
LW30D	30	30 mW	940 nm	110V AC/9V DC adapter only (no battery)	145 Hz pulse	~900 square mm	N/A	10 minutes

Intended Use:

To provide infrared light energy that penetrates the skin to promote increased blood flow and circulation, thereby, providing temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, and muscle spasm. The elevated tissue temperature also promotes relaxation of muscles and relief from pain resulting in improved range of motion.

SE Comparison:

Comparative Information

Feature	Model LW10D	Model LW30D	TDP Infrared Lamps	The LightPatch
510(k)			K020851	K993684
Product Code	ILY	ILY	ILY	ILY
Manufacturer	Skytech	Skytech	C&H Intl. Houston, TX	BioScan, Inc. Corrales, NM
Indications for Use	Infrared light energy to promote increased blood flow and circulation, providing temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, and muscle spasm. Promotes relaxation of muscles and relief from pain resulting in improved range of motion.	Infrared light energy to promote increased blood flow and circulation, providing temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, and muscle spasm. Promotes relaxation of muscles and relief from pain resulting in improved range of motion.	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. Help muscle spasms, minor sprains, and minor muscular back pain.	Personal comfort, temporary relief of minor aches and pains in muscles and joints. Aids in relaxation in muscles, temporary infrared range and freedom of motion, temporary minor pain relief, temporary increase in local blood circulation.
Portable	Yes	Yes	Yes	Yes
Infrared Lamps (LED)	Yes	Yes	Yes	Yes
Power Source	9V DC battery or 110V AC adapter, UL listed	110V AC adapter (only), UL listed	110V AC	9V DC battery
Wavelength	940 nm	940 nm	940 nm	940 nm
Treatment area	~225 square mm	~900 square mm	~1215 square mm	~6500 square mm

510(k) Substantial Equivalence Rationale:

1. The Skytech devices have the same indications for use as the predicate devices, TDP Infrared Lamp and the LightPatch.

2. The same technological characteristics are used for this device and the two predicates. All are based on the mode of operation that light emitting diodes convey heat energy to the skin. The device LEDs all operate at 940nm.

3. The comparative information shown in this submission demonstrates substantial equivalence for indications for use, design, and mode of operation.

Nonclinical Data:
A Risk Analysis was performed on all models using EN1441. Potential hazards are identified and have been mitigated by design and labeling.

The devices were tested for performance and found to raise skin temperature safely when used following the manufacturer's instructions. The rise in skin temperature results in the indications for use.

Adapters to convert 110V power to 9V or 12V are UL listed to assure user safety.

Conclusions:
These infrared lamp models are designed, labeled, and verified for performance and safety. The design has been tested and verified to raise the skin temperature adequately to effect the indications for use. A Risk Analysis confirms the design process and final product design for consideration of potential hazards. The potential hazards have been adequately addressed and mitigated by the design or by labeling. Labeling covers the user instructions and warning statements for users.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Skytech Enterprises, Inc.
C/o Mr. Lewis Ward
L.W. Ward and Associates, Inc.
4655 Kirkwood Court
Boulder, Colorado O 80301

Re: K024027
Trade/Device Name: Lightwave Infrared Lamps LW10D and LW30D
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: October 15, 2003
Received: October 21, 2003

Dear Mr. Ward:

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 Mark N Milhorn

Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Initial 510(k):

Device Name:

Indications for Use:

To provide infrared ~~light~~ lamp energy that penetrates the skin to promote increased blood flow and circulation, thereby, providing temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, and muscle spasm. The elevated tissue temperature also promotes relaxation of muscles and relief from pain resulting in improved range of motion.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

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

(510(k) Number K024027

Prescription Use___ _____ OR Over-the-Counter Use ____X____
(Per 21 CFR 801.109)