NOV 2 0 2003 510(k) Summary K0 33035

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the Medical Devices User Fee Act of 2002.

1. The sponsor of this premarket notification is:

   George Works
   President
   TLC Marketing Inc.
   12407 MoPac Ex. N
   Suite 100-413
   Austin, TX 78758

2. The submitter is:
   Robert J. Mazzaferro
   Manager
   RegTech Solutions, LLC
   Consultant for TLC Marketing Inc.
   11 Dellcastle Court
   Montgomery Village, MD 20886

This summary was prepared on September 29, 2003.

3. The name of the device is the TLC Infrared Lamp in two models, Whole Body Model ULK-H and the Topical Model ULT-H. These devices 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.

4. The above device is substantially equivalent to the Model CGQ-222B TDP infrared lamp and the other models that were cleared in K020851.

5. The ULK-H and ULT-H lamps each contain a number of quartz bulbs with ceramic coatings that when heated emits infrared radiation with wavelengths from 8 to 40 microns (8,000 to 40,000 nanometers).

6. The technological characteristics of the device are similar to those of the predicate device which has a metal ceramic-coated plate which when heated emits infrared radiation with wavelengths from 1 to 25 microns (1,000 to 25,000 nanometers).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

TLC Marketing, Inc.
C/o Mr. Robert J. Mazzaferro
Manager
RegTech Solutions, LLC
11 Dellcastle Court
Montgomery Village, Maryland 20886

Re: K033035
Trade/Device Name: TLC Models ULK-H and ULT-H Infrared Lamps
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: September 29, 2003
Received: September 29, 2003

Dear Mr. Mazzaferro:

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,

Miriam C. Provost

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

Enclosure

510(k) Number (if known): K033035

Device Name: Infrared Lamp

Indications for Use:

This device is intended to 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.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation

Miriam C. Provost

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

510(k) Number K033035