K041364 1/2

DEC 1 3 2004

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

ML830®*d* – PRELIMINARY STATEMENT

The **ML830®*d***

Applicant seeks market clearance for a device that is already cleared by another applicant, Light Force Therapy, Inc. under K022888. However, Applicant seeks the right to market that same device without making reference to the original applicant or its labeling.

I. Applicant:

MicroLight Corporation of America
2935 Highland Lakes Drive
Missouri City, Texas 77459

Contact Person: Fred A. Simpson, Esq.
c/o Jackson Walker L.L.P.
713-752-4248 telephone
713-752-4221 facsimile
e-mail fsimpson@jw.com

Date Prepared: September 22, 2004

II. Device Name

Proprietary Name:	**ML830®*d***
Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.550)
Product Code:	NHN

III. Predicate Device

The **ML830®*d*** is substantially equivalent to the Dio LFT 3000 cleared by the Agency under K022888. The manufacturer of the Dio LFT 3000 has agreed to supply MicroLight Corporation of America with the Dio LFT 3000 units which MicroLight will specifically label with the designation "**ML830®*d***" and publish and distribute with independent sales literature and instructions for use.

IV. Intended Use of the Device

The MicroLight **ML830®*d*** contains infrared lamps that are indicated for use 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 joint

pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

V. Description of the Device

The **ML830®*d*** is an innovative, safe, easy to use, hand-held, non-invasive device designed for in-home use. The device weights approximately ¾ pound and has a total treatment area of approximately 5 square inches (34 square centimeters).

The **ML830®*d*** contains 12 light emitting diodes and 12 infrared diodes with wavelengths of 660 nanometers and 880 nanometers, respectively, with total or maximum power output of approximately 500 milliwatts.

VI. Summary of the technical characteristics of the ML830®*d* to the referenced predicate devices.

The **ML830®*d*** is identical to the Dio LFT 3000 marketed by Light Force Therapy, Inc. Therefore, the **ML830®*d*** has identical technological characteristics as the predicate device. The only difference is that the **ML830®*d*** will be marketed under MicroLight's brand name.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2004

MicroLight Corporation of America
c/o Mr. Fred A. Simpson, Esq.
Jackson Walker L.L.P.
1401 McKinney Street, Suite 1900
Houston, Texas 77010

Re: K041364
Trade/Device Name: ML830®*d*
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: September 22, 2004
Received: September 23, 2004

Dear Mr. Simpson:

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 (240) 276-0115. 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, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX B

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K041364

Device Name: ML830®*d*

Indications for Use: **MicroLight Corporation of America's "ML830®*d*" is an infrared lamp that is indicated for use 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 joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: YES OR Over the Counter Use:
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)

510(k) Number K041364

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041364