K010175

FEB 0 6 2002

510(k) Summary
as required by section 807.92(c)

Submitted by: MicroLight Corporation of America
2935 Highland Lakes Drive
Missouri City, Texas 77459
Phone: 281-433-4648
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Contact Person: Michael M. Barbour

Prepared On: January 20, 2002

Classification Name: Lamp, Infrared

Common or Usual Name: Infrared Laser

Proprietary Name: MicroLight 830

Classification: The subject device satisfies the 21 CFR definition of a Class II infrared lamp as follows:

Regulation Number	Classification Number	Product Nomenclature	Identification/ Classification
890.5500	ILY	Lamp, Infrared	A device that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

Substantial Equivalence: The MicroLight 830 is substantially equivalent to the Super Nova, Acubeam marketed by Light-Force Therapy, which was the subject of 510(k) number K001179. The MicroLight 830 has the equivalent intended use (i.e. pain relief) and different technological characteristics (addressed by clinical data).

Device Description: The MicroLight 830 is a hand-held, battery operated, non-invasive, non-thermal, low energy, infrared laser, therapeutic medical device.

Statement of Indication For Use: The MicroLight 830 Laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

MicroLight 830 Study

In 1998 the MicroLight Corporation embarked on a double blind study for the use of low level lasers in the treatment of Carpal Tunnel Syndrome. The study protocol targeted approximately 135 patients diagnosed with carpal tunnel syndrome with moderate to severe symptoms, with a mean Symptom Severity Scale score of at least 2.0, with a score of at least 30 on a 100 point VAS pain scale, who have failed conservative therapy for at least one month and who have not had previous carpal tunnel release surgery. One half of the study subjects received treatment with the active laser and one half received treatment with a placebo laser.

Patients were treated three times a week for five weeks. Follow up times were 1, 6, and 12 weeks after the last treatment, at which time information was recorded on each patient. Once the study was completed a statistical analysis l was performed on the active and placebo groups.

Treatment was considered successful if a patient showed a 30% or more reduction in VAS pain score at the 12 week follow-up point. By this definition, the MicroLight laser successfully treated 55.8% of the patients in the active group, compared to 40.0% success for patients in the placebo group. No adverse effects from the MicroLight 830 treatment were noted.

	Percent of Patients	
IMPROVEMENT	MicroLight	Placebo
Any	75.6%	69.3%
30% or more	55.8%	40.0%
50% or more	45.3%	29.3%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Michael Barbour, President, CEO
MicroLight Corporation of America
2935 Highland Lakes
Missouri City, TX 77459

Re: K010175
Trade/Device Name: MicroLight 830 Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, Non-Heating, for Adjunctive Use in Pain Therapy
Regulatory Class: Class II
Product Code: NHN
Dated: December 3, 2001
Received: December 5, 2001

Dear Mr. Barbour:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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

510(k) Number: K010175

Device Name: MicroLight 830™ Laser System

Indications For Use:: The MicroLight 830 Laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Melkerson

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

510(k) Number K010175