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510(k) Summary

1. Applicant

Amest Corporation
30394 Esperanza
Rancho Santa Margarita, CA 92688

Contact person:
John Iest
Amest Corporation
30394 Esperanza
Rancho Santa Margarita. CA 92688
949-766-9692 ext 11

Date prepared: August 31, 2004

2. Device name

Proprietary name:	MB BioEnergy Light Therapy System
Common name:	Light Therapy System
Classification:	Infrared lamp (21 CFR 890.5500)
Product Code:	ILY

3. Substantially Equivalent Devices

1. K020017 –	MedX Health Corp. MedX 1000 Series Infrared Lamp
2. K014208	Russian American Technology Associates, Inc., SSIR Lamp

4. Device Description:

The MB BioEnergy Light Therapy System provides easy to use front panel controls and display for the operation of an array of infrared light emitting diodes that can apply topical heat to areas of the patient body. The user can set the frequency of oscillation, intensity level, and time of operation to control delivery of the radiation.

5. Intended use:

The MB System is a device that emits energy in the infrared spectrum to provide temporary increase in local blood circulation, temporary relief of muscle pain, spasms and stiffness, temporary relief of minor pain and joint aches associated with arthritis, and relaxation of muscles.

6. Comparison of technological characteristics with predicate device:

The MB BioEnergy Light Therapy System and the MedX 1000 Series and the SSIR System all use LEDs to provide IR energy to generate topical heating to elevate temperature. The treatment from all of these devices is designed to provide relief of muscle pain and strains. All devices have the same method of treatment, have similar indications for use, and provide the same general controls for administration of topical heating.

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7. Conclusion

The MB BioEnergy Light Therapy System is substantially equivalent to the predicate devices, has been tested to support compliance with industry standards, and therefore raises no new issues of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 29 2004

Mr. John Iest
President
Amest Corporation
30394 Esperanza
Ranch Santa Margarita, California 92688

Re: K030275
Trade/Device Name: MB BioEnergy Light Therapy System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: August 30, 2004
Received: August 31, 2004

Dear Mr. Iest:

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

Indications for Use

510(k) Number (if known): K030275

Device Name: MB BioEnergy Light Therapy System

Indications for Use:

The MB System is a device that emits energy in the infrared spectrum to provide temporary increase in local blood circulation, temporary relief of muscle pain, spasms and stiffness, temporary relief of minor pain and joint aches associated with arthritis, and relaxation of muscles.

Prescription Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

510(k) Number K030275