K020017

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JUL 12 2002

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant: MedX
MedX Health Corp.
3535 Laird Road, Unit 2
Mississauga, ON
Canada
L5L 5Y7

Phone: 1 905 826-0766
Fax: 1 905-826-0086

Contact Person: Anita Saltmarche

Prepared on: July 10th, 2002

Model No./Name: MedX 1000 Series

Classification: Lamp, Infrared - 89 ILY
Physical Medicine Device, 21 CFR 890.5500 (Class II)

Predicate Device: LightForce Therapy, Acubeam K001179

Device Description

MedX 1000 Series equipment consists of a console - (MBM 1050) and two different light emitting diodes (LED) accessories - (MCT 150 and MCT 600). The console unit supports the LED semiconductors and assembly, electronics, control panel and labels. The features of the accessories include energy emitted in the near infrared spectrum to provide therapeutic heating.

Statement of Intended Use for MedX 1000 Series:

The MedX 1000 Series is an infrared lamp. The energy emitted provides topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

Technological Characteristics Summary

Testing for the MedX 1000 Series has been carried out in the areas of mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, temperature control and irradiation distribution patterns. The device has been found to be safe in all areas for the intended use.

The MedX Health Inc., MedX 1000 Series is substantially equivalent to the LightForce Therapy Acubeam product in that it has the same intended use as the Light Force Therapy product, but slightly different technical characteristics,. This is a differences in power source with the Light Force Therapy products are battery-operated devices operated where as the MedX 1000 series operates on grounded current, and provides continuous frequency. These differences in technical characteristics do not materially impact the safety or effectiveness of the device. Hence the MedX 1000 Series is substantially equivalent to the LightForce Therapy Acubeam.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Anita Saltmarche, Vice President
Clinical and Scientific Affairs
MedX Health Corporation
3535 Laird Road, Unit 2
Mississauga, Ontario
Canada L5L 5Y7

Re: K020017
Trade/Device Name: MedX 1000 Series
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: April 30, 2002
Received: May 1, 2002

Dear Ms. Saltmarche:

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,

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

INDICATION FOR USE

Indication for Use

The MedX 1000 Series is an infrared lamp, as per 21 CFR 890.5500. It emits energy to provide topical heating for temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, and minor pain and stiffness associated with arthritis. For use when heat is indicated for the treatment of the fore mentioned conditions.

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

510(k) Number K020017