



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Barnes
President
Micro Health Systems, Inc.
407 Dover Lane
Parkland, Florida 33067

AUG 13 2002

Re: K021956
Trade/Device Name: MHS Med Light 1000
Regulation Number: 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: July 29, 2002
Received: August 7, 2002

Dear Mr. Barnes:

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.

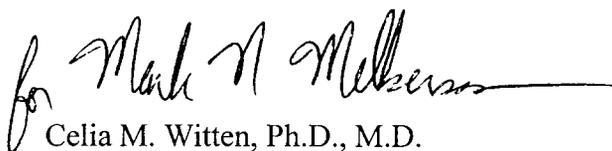
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned above the typed name.

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 (if known): K021956

Device Name: MHS MED LIGHT 1000

Indications For Use:

The Micro Health Systems, MHS MED LIGHT 1000 is a device which helps to temporarily increase local blood circulation where applied, and temporarily relieves minor muscle and joint aches and pains through the use of heat applied in a non-contact manner. Aiming means adjustable by users from the heat ceramic filament in which there is no hazard for contacting high temperature lamps. An adjustable timer control for safety functions is also incorporated into the MHS MED LIGHT 1000. The Micro Health System MHS MED LIGHT 1000 cooling method is related to temperature of the enclosure, and the enclosure, and the enclosure temperatures of the three devices listed in the comparison table are assured. According to the different wattages and the maximum temperatures, we also know the ceramic type lamp of the AP-2018 is more efficient than the other two lamps.

The maximum temperatures for these three devices listed in the comparison table are above 100 degrees Fahrenheit, and can reach the intended results. The timer controls and the continuous intensity controls exist on the MHS MED LIGHT 1000. The user can control the timer function and intensity control to control the receiving heat amount, thus assuming the safety level.

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

Concurrence of CDHR of Device Evaluation (ODE)

(Division Sign- Off)
Division Of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number _____

Prescription Use _____

or

Over-the-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N. Millar

(Division Sign-Off)
Division of General Surgery
and Neurological Devices

510(k) Number K021956