OCT 7 - 2004

K042554

AUTO*THERM® 390, MODEL ME 390
510(K) SUMMARY STATEMENT (KXXXXXX)

Submitter's Name: Mettler Electronics Corp.
Address: 1333 South Claudina Street
Anaheim, CA 92805

Telephone: 714-533-2221

Contact: Robert E. Fleming
Director, QA/RA

Date Prepared: August 31, 2003

Proposed Device Name:

a. TRADE NAME: Auto*Therm® 390, Model ME 390
b. CLASSIFICATION NAME: Shortwave Diathermy
c. COMMON NAME: Shortwave Diathermy

Predicate Device:

a. TRADE NAME: Auto*Therm 395, Model 395
b. 510(k) Number: K

Description of Proposed Device:

The Auto*Therm 390 is a shortwave diathermy device that operates at 27.12 MHz. It provides shortwave diathermy therapy using condenser and electromagnetic inductive coil fields in both continuous and pulsed modes of operation. It is suited for all diathermy treatments in both the clinic and medical practice.

The ME 390 is portable and easily transportable between treatment rooms. A four-wheel cart is provided when the optional induction electrode and arm are used. Two of these wheels have brakes that can be locked to prevent movement during use. The membrane control panel is mounted on the top of the unit. It is easily cleaned and contains all the controls and displays for operating the Auto*Therm 390.

The intensity control knob adjusts the output power via an encoder. The power switch is on the upper left side of the unit. Screw holes for attaching the arms are located on the rear of the unit. The sockets for connecting cables for the condenser and inductive coil applicators and the detachable mains power supply cable including fuses are also located on the back of the unit. The ripcord for the patient emergency-OFF switch passes through a bushing mounted on the back of the unit so that it can be pulled from all directions.

AUTO*THERM® 390, MODEL ME 390
510(K) SUMMARY STATEMENT (KXXXXXX)

Proposed Device Intended Use Statement:

510(k) Number: TBD

Device Name: Auto*Therm® 390, Model ME 390

Indications for use:

1. Pain relief
2. Reduction of muscle spasm
3. Localized increase in blood flow
4. Increase range of motion of contracted joints.

Comparison of Technological Characteristics Between Proposed and Predicate Devices: (see following page)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Mr. Robert E. Fleming
Regulatory Compliance Manager
Mettler Electronics Corporation
1333 South Claudina Street
Anaheim, California 92805

Re: K042554
Trade/Device Name: Auto* Therm 390 (ME390)
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy Device
Regulatory Class: II
Product Code: IMJ
Dated: September 17, 2004
Received: September 21, 2004

Dear Mr. Fleming:

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.

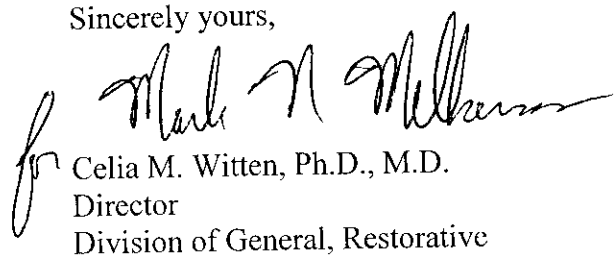
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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,



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): K042554

Device Name: Auto*Therm 390 (ME390)

Indications For Use:

Shortwave diathermy delivers energy in the radio band of 27.12 MHz to provide deep heating therapeutic effects to body tissues. When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as:

1. Relieving pain
2. Reducing muscle spasm
3. Increasing range of motion of contracted joints using heat and stretch techniques.
4. Increasing blood flow to tissues in the treatment area.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K042554