DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 9 1999

Mr. Robert E. Fleming
Director of Operations and Regulatory Affairs
Mettler Electronics Corporation
1333 South Claudina Street
Anaheim, California 92805

Re: K984114
Trade Name: Sys*Stim® ME294
K984142
Trade Name: Sonicator Plus 992 (ME992) and Sonicator Plus 994 (ME994)
Regulatory Class: II
Product Codes: IPF, LIH, and GZJ
Dated: November 16, 1998
Received: November 17 and 18, 1998

Dear Mr. Fleming:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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). You may, therefore, market the devices, 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.

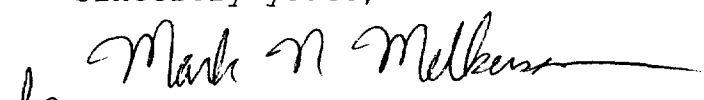
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 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 devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K984142

Device Name: Sonicator Plus 992 (ME992) & Sonicator Plus 994 (ME994)

Indications For Use:

Therapeutic Ultrasound

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

Neuromuscular Stimulation

1. Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (Interferential, Premodulated and Microcurrent waveforms)
2. Temporary relaxation of muscle spasm, *(all waveforms except Microcurrent)*
3. Prevention of post–surgical phlebo–thrombosis through immediate stimulation of calf muscles, *(all waveforms except Microcurrent)*
4. Increase of blood flow in the treatment area, *(all waveforms except Microcurrent)*
5. Prevention or retardation of disuse atrophy in post–injury type conditions, *(all waveforms except Microcurrent)*
6. Muscle re–education, *(all waveforms except Microcurrent)*
7. Maintaining or increasing range of motion, *(all waveforms except Microcurrent)*

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

Concurrent of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984142

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)