DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1996

Ms. Kathy L. Hann
QA/Regulatory Manager
Mercury Medical®
11300A-49th Street North
Clearwater, Florida 34622-4800

Re: K954492
Trade Name: Mercury Expiratory Resistance Exerciser
Regulatory Class: II
Product Code: 73BWF
Dated: July 9, 1996
Received: July 17, 1996

Dear Ms. Hann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent 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 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 device 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 device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (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 at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

MERCURY MEDICAL®

K954492

REVISED
ENCLOSURE I
510 (k) SUMMARY

OCT 21 1996

- Mercury Expiratory Resistance Exerciser (RESISTEX®)
- Common Name - Expiratory Resistance Exerciser and Adapter
- Classification Name - Spirometer, Therapeutic

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21CFR897.92. The Mercury Expiratory Resistance Exerciser, when placed in-line with an aerosol treatment, permits resistance breathing during aerosol treatment in a manner consistent with the Circulaire™ Aerosol Drug Delivery System by Westmed.

TABLE OF COMPARISON

	MERCURY EXPIRATORY RESISTANCE EXERCISER	WESTMED CIRCULAIRE™ AEROSOL DRUG DELIVERY SYSTEM
INTENDED USE	PERMITS RESISTANCE BREATHING DURING AEROSOL TREATMENT	PERMITS RESISTANCE BREATHING DURING AEROSOL TREATMENT
MATERIALS MODE OF OPERATION	STYRENE & LDPE ROTATING RESISTANCE ORIFICE WITH IN-LINE NEBULIZER	POLYPROPYLENE ROTATING RESISTANCE ORIFICE WITH IN-LINE NEBULIZER
ONE WAY VALVE	BETWEEN NEBULIZER AND EXHALATION RESISTOR	BETWEEN NEBULIZER AND EXHALATION RESISTOR
PROVIDES POSITIVE EXPIRATORY PRESSURE BENEFIT DURING TREATMENT	HAS VARIABLE RESISTANCE ADJUSTMENT	HAS VARIABLE RESISTANCE ADJUSTMENT
PATIENT CONNECTION	LDPE MOUTHPIECE	LDPE MOUTHPIECE
PACKAGING	SINGLE PACKED 20/BOX	SINGLE PACKED 25/BOX

Arthur J. Ward

10/18/96
Date

11300A-49th Street North • Clearwater, Florida 34622-4800 • 813-573-0088