

K972213

MAR 13 1998

Statement on the Safety and Effectiveness of the MS-700

1. Safety

A) For the Subject

Since this device operates in exactly the same manner as any other standard oscillometric blood pressure measure device, it presents no special safety concerns for the patient. The device is equipped with an emergency deflation valve which can be opened immediately with the pressing of a single function key if the patient should feel any discomfort during the test. Any rapid change in electric power also causes the emergency valve to be opened immediately. No electrical components come in direct contact with the subject.

B) For the Operator

This device can be operate by the subject. If it is operated by someone other than the subject, the operator faces the same safety concern as the subject.

C) Additional Safety Information

Additional safety information on the MS-700 can be found in Section D (Physical and Environmental Testing Results) and Section E (Software Development Standards and Quality Assurance) of the 510(k) submission.

2. Effectiveness

Effectiveness information on the MS-700 can be found in Section C (Clinical Studies) of this submission. Additionally, per the Safe Medical Devices Act of 1990, Mars Metal Company, Ltd. will provide safety and effectiveness information on the MS-700 to interested persons upon request. This information will include adverse safety and effectiveness information that is relevant to a assessment of substantial equivalence. The information provided on request will also include clinical testing information.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alan S. Lee
US Representative
Mars Metal Co., Ltd.
2121 W. Beacon Avenue
Anaheim, CA 92804

MAR 13 1998

Re: K972213
MS-700
Regulatory Class: II (Two)
Product Code: 74 DPW
Dated: December 12, 1997
Received: December 15, 1997

Dear Mr. Lee:

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 (for the indications for use stated in the enclosure) 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 Current Good Manufacturing Practice requirements, 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 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.

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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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



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

Enclosure

510(k) Number (if known): K972213

Device Name: MS-700 Automatic Digital Blood Pressure Monitor

Classification Panel: Class II 74 DXN 870.1130

Indications for Use:

The *MARS MS-700 Automatic Digital Blood Pressure Monitor* is designed to provide signals from which systolic and diastolic pressures can be derived through the use of the oscillometric method. The device also measures the heart rate.

The device is for adult use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use _____

DA Spivey for DLL

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K972213