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**510(k) SUMMARY FOR
MATSUSHITA ELECTRIC CORPORATION OF AMERICA'S
BLOOD PRESSURE MONITORS,
MODEL EW243 AND MODEL EW254**

I. SYSTEM SPONSOR

A. Sponsor Name and Address

Matsushita Electric Corporation of America (MECA)
One Panasonic Way (4A-3)
Secaucus, NJ 07094

B. Official Correspondent and Address

Edward M. Basile, Esq.
King & Spalding
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006
Phone: (202) 737-0500
Fax: (202) 626-3737

II. SYSTEM IDENTIFICATION

A. Classification Name

Non-invasive blood pressure measurement system

B. Common/Usual Name

Electronic blood pressure monitor

C. Trade/Proprietary Name of the System

Panasonic blood pressure monitor, model EW243
Panasonic blood pressure monitor, model EW254

D. Classification

Regulatory Class: II (two); 21 C.F.R. § 870.1130

Classification Panel: Circulatory Systems Device Panel

Product code: 74 DXN

III. PREDICATE DEVICE

In 1995, MECA's wrist blood pressure monitor model EW277 was cleared for market (K942422).

A. Name of Predicate Devices

Panasonic wrist blood pressure monitor, model EW277.

B. Intended Use

The wrist blood pressure monitor is intended to measure systolic and diastolic blood pressure using a pressurized cuff.

C. Device Description

The blood pressure monitor is a battery-operated, non-invasive, digital, electronic blood pressure monitor.

IV. DEVICE DESCRIPTION

MECA intends to market two battery-operated, non-invasive, digital, electronic, arm blood pressure monitors, model EW243 and model EW254.

V. INTENDED USE

Model EW243 and model EW254 are intended to measure systolic and diastolic blood pressure using a pressurized cuff.

VI. SUBSTANTIAL EQUIVALENCE COMPARISON

A. Intended Use

The intended use for model EW243 and model EW254 is identical to that of MECA's 510(k)-cleared blood pressure monitor model EW277.

B. Technological Characteristics

1. Similarities between Model EW277, EW243, and EW254

MECA modified its existing, previously-cleared blood pressure monitor model EW277, to create model EW243 and model EW254. Therefore, these device models share many of the same features, functions, and components.

2. Differences between Model EW277, EW243, and EW254

Model EW277 is a blood pressure monitor that has a cuff that is worn around the wrist, while both model EW243 and EW254 have cuffs that are worn around the upper arm. The cuff circumference for model EW277 is smaller than the cuff circumference for models EW243 and EW254 (135-195 mm for EW277 to 200-400 mm for EW243 and EW254). The size and weight for these devices are also different. While these devices use the same blood pressure measurement algorithm, the values for the matrix table and constants have been modified to account for differences in the volume and pressure in the arm.

VII. PERFORMANCE DATA

Hardware and software testing was conducted to verify that the changes made to model EW234 and EW254 do not affect the safety and effectiveness of these devices. Model EW243 and model EW254 passed all tests. Additionally, a clinical study was conducted using model EW254. This study demonstrates that MECA's arm blood pressure monitors can accurately measure blood pressure.

VIII. CONCLUSIONS

MECA's arm blood pressure monitors, model EW243 and model EW254, are substantially equivalent to MECA's previously-cleared wrist blood pressure monitor model EW277.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2000

Matsushita Electric Corporation of America
c/o Mr. Edward M. Basile
King & Spalding
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-0500

Re: 510(K) K991458
MECA Blood Pressure Meter, Model EW243 and Model EW254
Regulatory Class: II
Product Code: DXN
Dated: January 19, 2000
Received: January 19, 2000

Dear Mr. Basile:

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 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). 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.

Page 2 - Mr. Edward M. Basile

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) 594-4639. 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 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/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K991458

Device Name: MECA arm blood pressure meters, model EW243 and model EW254

Indications For Use:

Model EW243 and model EW254 are intended to be used for the oscillometric PRECISE LOGIC™ measurement of systolic and diastolic blood pressure and pulse rate using a pressurized cuff.

These devices are designed for use by adults. These devices should not be used on infants or toddlers, for continuous monitoring during medical emergencies or operations, or for any other purpose other than measuring blood pressure.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or Automated Sphygmomanometers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K 991458

(Optional Format 3-10-98)