

3/3/99

K981542

**510(k) SUMMARY FOR
PANASONIC CORPORATION'S WRIST BLOOD PRESSURE METER,
MODEL EW284**

I. SYSTEM SPONSOR

A. Sponsor Name and Address

Panasonic Corporation (Panasonic)
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 meter

C. Trade/Proprietary Name of the System

Panasonic wrist blood pressure meter, model EW284

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

A. Name of Predicate Devices

Panasonic wrist blood pressure meter, models EW273, EW277, EW278, and EW279.

B. Device Description

The wrist blood pressure meter is a battery-charged non-invasive digital electronic blood pressure meter manufactured by Matsushita Electric Works, Ltd., (MEW) Osaka, Japan. The wrist blood pressure meter is intended to measure systolic and diastolic blood pressure using a pressurized cuff worn around the wrist.

IV. BACKGROUND

In 1995, the Panasonic wrist blood pressure meter models EW273, EW277, EW278, and EW279 were cleared for market (K942422). Panasonic intends to market an additional device, model EW284. This model is substantially equivalent to Panasonic's previously cleared devices.

V. DEVICE DESCRIPTION

Model EW284 is a wrist blood pressure meter.

VI. INTENDED USE

Model EW284 is intended to measure systolic and diastolic blood pressure using a pressurized cuff worn around the wrist.

VII. SUBSTANTIAL EQUIVALENCE COMPARISON

Intended Use

The intended use for model EW284 is identical to that of Panasonic's 510(k) cleared wrist blood pressure meter models.

Technological Characteristics

The design of model EW284 is the same as Panasonic's previously cleared wrist blood pressure meter models EW273, EW277, EW278, and EW279. Minor modifications were made to product specifications to harmonize with Japan Industry Standards (JIS). The measurement range, display functionality, and device dimensions were also modified for ease of use. Data memory and retention have increased from 30 to 60 readings. Three buttons and a switch were added. The recall, memory, and memory clear buttons can be

used to obtain or delete pulse rate information that is stored in memory. The “J” switch allows the user to control whether audible tones are provided during measurement, when an error occurs, and at the conclusion of the measurement. Differences between model EW284 and Panasonic’s previously cleared devices are described in Table 1.

VIII. PERFORMANCE DATA

Hardware and software testing was conducted to verify that the changes made to model EW284 have not affected the safety and effectiveness of this device. All devices passed all tests and are qualified for use.

IX. CONCLUSIONS

The Panasonic Corporation wrist blood pressure meter, model EW284, is substantially equivalent to previously cleared Panasonic Wrist Blood Pressure Meter models EW273, EW277, EW278, and EW279.

TABLE 1
DIFFERENCES BETWEEN MODEL EW279 and MODEL EW284

FEATURE	EW279 Predicate device	EW284
Main body (w) x (h) x (d)	7 x 3 x 7 (inches)	3 x 3 x 1 (mm)
Display: during measurement	“▲” lights up under “MEAS”	“♥” lights up at the right side of display
Display: error indication; excessive pressurization; no pulse detection	“▲” lights up under “ERR”	“E” lights up at the center of diastolic blood pressure indication
Measurement range of pressure	20-300 mm Hg	0-300 mm Hg
Noise safety specification	Less than 65 dB at 50 cm from main unit	Less than 65 dB at 1 m from main unit
Error margin performance specification	± 2 beats/min	± 5 beats per min
Pressurization performance specification	Pressurization time from 0 to 150 shall be less than 10 seconds	Pressurization time from 0 to 180 shall be less than 20 seconds
Data memory and retention	Memory function for 30 readings. Device retains up to 30 readings in memory.	Memory function for 60 readings. Device retains up to 60 readings in memory.
Additional operational buttons/switches	Not applicable	Recall button Memory button Memory clear button “♪” switch



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Panasonic Corporation
c/o Mr. Edward M. Basile, Esq.
King & Spalding
1730 Pennsylvania Avenue, N.W.
Washington, DC 20006-4706

Re: K981542
Panasonic Wrist Blood Pressure Meter, Model EW284
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: February 12, 1999
Received: February 12, 1999

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, Esq.

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" (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,



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): K981542

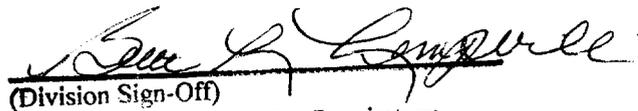
Device Name: Panasonic Wrist Blood Pressure Meter, model EW 284

Indications For Use:

The Panasonic wrist blood pressure meter, model EW 284, is intended to measure systolic and diastolic blood pressure using a pressurized cuff worn around the wrist.

(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 K981542

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)