3/3/99

K981431

510(k) SUMMARY FOR PANASONIC CORPORATION'S WRIST BLOOD PRESSURE METER, MODEL EW280

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 EW280

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 EW280. This model is substantially equivalent to Panasonic's previously cleared devices.

V. DEVICE DESCRIPTION

Model EW280 is a wrist blood pressure meter.

VI. INTENDED USE

Model EW280 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 EW280 is identical to that of Panasonic's 510(k) cleared wrist blood pressure meter models.

Technological Characteristics

The design of model EW280 is the same as previously cleared Panasonic 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. Differences between model EW280 and Panasonic's previously cleared devices are described in Table 1.

TABLE 1
DIFFERENCES BETWEEN MODEL EW273 and MODEL EW280

FEATURE	EW273 Predicate device	EW280
Main body (w) x (h) x (d)	77 x 66 x 23 (mm)	67 x 67 x 26 (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
Method for displaying blood pressure value and pulse rate	Alternative	Simultaneous[1]
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
Operational buttons	2[2] "0/1" "start"	1 "0/1"

[1] Available in another predicate device (Model EW 279) which was cleared (K942422).
[2] Use of one operational button was cleared in 1995.

VIII. PERFORMANCE DATA

Hardware and software testing was conducted to verify that the changes made to model EW280 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 EW280, is substantially equivalent to previously cleared Panasonic Wrist Blood Pressure Meter models EW273, EW277, EW278, and EW279.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 1999

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

Re: K981431
Panasonic Wrist Blood Pressure Meter, Model EW280
Regulatory Class: II (Two)
Product Code: 74 DXN
Dated: February 12, 1999
Received: February 12, 1999

Dear Mr. Basile:

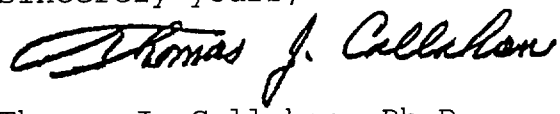
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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): K981431

Device Name: Panasonic Wrist Blood Pressure Meter, model EW280

Indications For Use:

The Panasonic wrist blood pressure meter, model EW280, 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)

K981431

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

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)