K110501
p1/3

MAR 2 1 2011

Omron Healthcare, Inc.
1200 Lakeside Drive
Bannockburn, IL 60015 USA

Tel – 847-247-5626
Fax – 847-680-6269

Official Contact: Mirna DiPano – Director, Quality & Regulatory

Proprietary or Trade Name: Model HEM-4030

Common/Usual Name: Noninvasive blood pressure measurement system.

Classification Name/Code: DXN –
Noninvasive blood pressure measurement system.
CFR 870.1130

Device: HEM-4030

Modified Device: Omron – HEM-405C - K903133

Device Description:
The HEM-4030 is a non-invasive blood pressure monitor that determines blood pressure by the oscillometric method. The cuff is manually inflated by the user with a squeeze bulb. The device is powered by 2 "AAA" batteries. It is a minor modification of the Omron – HEM-405C- 510(k) K903133 non-invasive blood pressure monitor.

The modifications to the device and labeling do not change the intended use of the predicate device. The modifications to the device do not alter the fundamental scientific technology. As there are no changes in hardware or software that will impact performance there is no need to validate the changes through a clinical investigation.

Indications for Use:
The HEM-4030 is a digital monitor intended for measuring systolic and diastolic blood pressure and pulse rate in adults.

The Omron HEM-4030 is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated

Environment of Use:
Home

Contraindications
None

Summary of Modifications
The modifications to the device and labeling do not change the intended use of the predicate device. The modifications to the device do not alter the fundamental scientific technology. As there are no changes in hardware or software that will impact performance, there is no need to validate the changes through a clinical investigation.

Modifications:

- Minor changes to environmental specifications
- Changes to physical dimensions
- Change to packaging for the physical characteristics of the new device.
- Change in pulse rate specification
- Change in pressure range
- Change in operating humidity
- Change in weight
- Minor changes to hardware
- Minor changes to software in support of new pulse rate and pressure range
- Change in cuff material
- Stores up 21 measurements in memory
- Electrical and mechanical changes to support change to operation on 2 "RO3" ("AAA") batteries instead of 4 "AA" batteries.
- Indicator if blood pressure is above certain limits

There are changes in the instructions for use to update and support the new model name and characteristics. Note there is no change in intended use, including patient population and environment of use. There is no change in contraindications.

Change to packaging for the physical characteristics of the new device.

There are no changes to the blood pressure or pulse rate algorithms.

Performance Testing
Verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met. **Table 5.1** summarizes the testing.

Table 5.1 – Performance Testing Performed

Parameter
Pressure Measurement Performance
Blood Pressure Measurement Accuracy
Re-inflation
Drift Correction
Battery Indicator Testing
Automatic Power Off
Clear and Display Memory
Memory Error Detection
Average Values
Indication of High Blood Pressure
Setting of pressure units of measure
Pressure unit of measure conversion
Saving units of measure
Communication Errors
RAM Testing
ROM Testing
No Blood Pressure determined
Blood Pressure out of range
Pulse Rate out of range
Pulse rate can't be determined
Deflation rate error
Cannot inflate cuff
Artifact
Unstable sensor
No arm
Measurement time exceeded
Pressure sensor errors
Test mode
Waveform checks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Omron Healthcare, Inc.
c/o Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

MAR 2 1 2011

Re: K110501
Trade/Device Name: Omron HEM-4030
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: February 19, 2011
Received: February 22, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

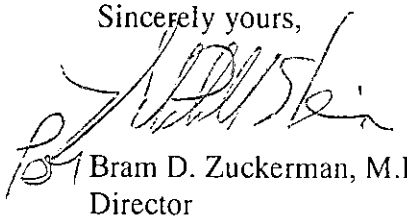
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110501

Indications for Use Statement

510(k) Number: **K110501**

Device Name: HEM-4030

Indications for Use:

The HEM-4030 is a digital monitor intended for measuring systolic and diastolic blood pressure and pulse rate in adults.

The Omron HEM-4030 is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

Prescription Use or **Over-the-counter use X**__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 3/21/2011
Division of Cardiovascular Devices
510(k) Number K110501