510(k) Summary
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JAN 16 2014

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Official Contact: Renee Thornborough – Director QA/RA

Proprietary or Trade Name: Model HEM-7311

Common/Usual Name: Noninvasive blood pressure measurement system.

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

21CFR 870.1130
Class II

Device: Model HEM-7311

Predicate Devices: Omron –BP742 (HEM-7200-Z) – K121932

Device Description:
The device is an automatic non-invasive blood pressure system. The device is battery powered and can also be powered from an IEC 60601-1 compliant AC adaptor. The device inflates a cuff with an integral pump, then deflates the cuff via an electronically controllable valve. During deflation the cuff pressure is monitored and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines pulse rate, as well as systolic and diastolic pressure.

The device is intended to be used with an Omron specified cuff to encompass arms ranging from 9 to 17 inches in circumference.

The device also detects the appearance of irregular heartbeats during measurement.

The device has provisions for selecting two users, measurements from these users are stored in memory. The memory stores up to 100 of the latest measurements. It can also display an average of the last three values.

Intended User
Home user

Patient Population
This device is intended for use on adults.

Indications for Use:
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environment of Use:
Home

Contraindications:
There are no known contraindications.

Predicate Device Comparison:

The HEM-7311was compared to the predicate BP742 (HEM-7200-Z) – K121932 in the device comparison table below.

Note that a number of documents in this submission include reference to the Cuff Wrapping Guide (or Cuff Wrapping Check). This feature has been removed from the device and is not part of this submission

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Device Comparison

	Predicate Device	New Device
Model Name:	**BP742(HEM-7200-Z)**	**HEM-7311**
510(k) Number	**K121932**	**TBD**
Indications	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. **Identical to predicate**
Environment of Use	Home	Home **Identical to predicate**
Patient Population	Adult	Adult **Identical to predicate**

Specifications / Features

	BP742(HEM-7200-Z)	HEM-7311
Measurement method / Principal of operation	Cuff oscillometric method	Cuff oscillometric method. **Identical to predicate**
Measurement range	Pressure: 0 to 299 mmHg Pulse Rate: 40 to 180 beats/min.	Pressure: 0 to 299 mmHg Pulse Rate: 40 to 180 beats/min. **Identical to predicate**
Pressure sensor	Semiconductor pressure sensor	Semiconductor pressure sensor. **Identical to predicate**
Applicable cuff (Arm Circumference)	22-42cm	(small 17-22cm), standard (22-32cm) and (large 22-42cm) **, similar to predicate, additional range clinically validated**
Accuracy of pressure indicator	Within ±3 mmHg or 2 % of reading	Within ±3 mmHg or 2 % of reading **Identical to predicate**
Accuracy of pulse rate	Within ±5 % of reading	Within ±5 % of reading **Identical to predicate**

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	BP742(HEM-7200-Z)	HEM-7311
Inflation method	Automatic by electric pump	Automatic by electric pump. **Identical to predicate**
Deflation method	Automatic pressure release valve	Automatic pressure release valve **Identical to predicate**
Display	LCD digital display	LCD digital display **Identical to predicate**
Power Source	4"AA"batteries or AC adapter	4"AA"batteries or AC adapter **Identical to predicate**
Operating conditions	10 to 40 °C 15 to 90 %RH	10 to 40 °C 15 to 90 %RH **Identical to predicate**
Storage conditions	-25 to 60 °C 10 to 95 %RH	-20 to 60 °C 10 to 95 %RH **similar to predicate**
Dimensions (mm)	123(W) × 141(D) × 85 (H) mm	183 (W) × 230 (D) × 99 (H) mm, size is not a factor in function of the device
Weight	Approx. 340g (not including battery)	Approx. 640g (22 5/8 oz) (not including battery), weight is not a factor in function of the device.
Irregular Heart beat Feature	Yes	Yes, **Identical to predicate**
Body movement detection	Yes	Yes, **Identical to predicate**
Hypertension indicator	Yes	Yes, **Identical to predicate**
TruRead™	No	Provides an average of 3 measurements

Technology / Features Comparison

	BP742(HEM-7200-Z)	HEM-7311
Power supply	Regulates power voltage regardless of battery voltage.	Regulates power voltage regardless of battery voltage. **Identical to predicate**

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	BP742(HEM-7200-Z)	HEM-7311
Microprocessor	• determines blood pressure and pulse rate • controls the pump, the valve, and the display • detects switch operations • stores measurement results • manages date and time	• determines blood pressure and pulse rate • controls the pump, the valve, and the display • detects switch operations • stores measurement results • manages date and time **Identical to predicate**
Pressure sensor	Semiconductor pressure sensor	Semiconductor pressure sensor, **Identical to predicate**
Rapid exhaust Valve	Automatic rapid air release valve.	Active electronic control valve that performs cuff air bleeding and release, **identical in function to predicate**
Deflation Valve	Automatic pressure release valve	
Inflation source	DC rolling pump	DC rolling pump **Identical to predicate**
Display	LCD (Liquid Crystal Display) displays; • current cuff pressure • systolic blood pressure • diastolic blood pressure • pulse rate • error messages • measurement results in the memory	LCD (Liquid Crystal Display) displays; • current cuff pressure • systolic blood pressure • diastolic blood pressure • pulse rate • error messages • measurement results in the memory **Identical to predicate**
Controls	• START/STOP Button • Date/Time setting Button • Up/Down Button • User ID Selections Button	• START/STOP Button • Date/Time setting Button • Up/Down Button • User ID Selections Button **Identical to predicate**
Cuff	Wide Range Cuff, Standard Adult Arm Cuff, Large Cuff	HEM-CS24 (small 17-22cm), HEM-CR24 (standard 22-32cm) and Soft Cuff HEM-RML31 (large 22-42cm)
Materials	Patient contact materials of the cuff have been cleared in the referenced 510(k)	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance

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Differences Between Other Legally Marketed Predicate Devices:
The Omron HEM-7311 is viewed as substantially equivalent to the predicate device because: The HEM-7311 uses the exact same technology and has identical indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications –
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.
The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
Discussion – These indications are identical to the predicate Omron BP742 (K121932).

Prescriptive – The HEM-7311 and predicate are OTC.

Design and Technology – The HEM-7311 has equivalent design and features when compared to the predicate and has the identical technology to the predicate.

Performance and Specifications – The HEM-7311 has equivalent specifications of performance when compared to the predicate.

Compliance with standards – The predicate device complies with SP10, IEC 60601-1 and IEC 60601-1-2. The HEM-7311 complies with AAMI ANSI ES6060-1 (which replaced IEC 60601-1), IEC 60601-1-2 and ANSI/AAMI/ISO 81060-2 (which replaced SP10). The HEM-7311 also complies with IEC 80601-2-30 and IEC 60601-1-11 for home healthcare.

Materials –
The patient contacting materials of the cuffs has been tested in accordance with ISO 10993-1 and FDA Guidance. The tests included Cytotoxicity, Sensitization, and Intracutaneous Reactivity.

Patient Population –
The HEM-7311 and predicate are indicated for adults

Environment of Use – Home, Identical to the predicate

Non-Clinical Testing Summary:

We have performed bench tests and found that the HEM-7311 met all requirements specifications and standards requirements and were found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing to insure the device meets its specifications
- Testing of hazard mitigations
- Testing for compliance to AAMI ANSI ES 60601-1
- Testing for compliance to IEC 60601-1-2
- Testing for compliance to IEC 80601-2-30
- Testing for compliance to IEC 60601-1-11
- Comparative Testing to the predicate

Clinical Testing Summary:
Testing to insure clinical accuracy of the device in accordance with ANSI/AAMI/ISO 81060-2 as documented in **Section 20.**
Eighty five patients (39males and 46 females) were recruited for the study.
Standard auscultation method was used as the reference blood pressure (BP) measuring in the left upper arm. BP measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in AAMI.

Substantial Equivalence Conclusion
Omron maintains that the HEM-7311 is substantially equivalent to the predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 16, 2014

Omron Healthcare, Inc.
c/o Paul Dryden
ProMedic, Inc
24301 Woodsage Dr.
Bonita Springs, FL 34134 US

Re: K133379
Trade/Device Name: Hem-7311
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 19, 2013
Received: November 20, 2013

Dear Paul 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Owen P. Faris -S

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

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: **Omron HEM-7311**

Indications for Use:

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.
The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environments of Use: Home
Patient Population: Adult

Prescription Use (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use _XX_** (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)

Digitally signed by Owen P. Faris -S
Date: 2014.01.16 10:10:39 -05'00'