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

April 20, 2017

Omron Healthcare, Inc.
% Paul Dryden, Consultant
Promedic, LLC
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K163235
Trade/Device Name: HEM-9210T
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 22, 2017
Received: March 23, 2017

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.

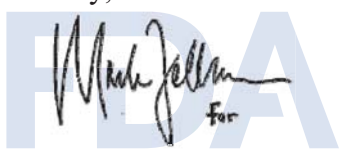
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Industry and Consumer Education 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 Industry and Consumer Education 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,



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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K163235

Device Name

Omron Healthcare HEM-9210T

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Omron Healthcare, Inc.
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Lake Forest, IL 60045 USA Fax- 847-680-6269

Official Contact: Renee Thornborough – Executive Director QA/RA

Proprietary or Trade Name: Model HEM-9210T

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-9210T

Predicate Device: Omron –HEM-7311 – K133379

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 Omron specified cuffs as specified below

- Small 17-22cm arm cuff - circumference (PN: HEM-CS24)
- Medium 22-42cm arm cuff - circumference (PN: HEM-RML31)
- Extra Large (XL) cuff arm circumference 42-50cm (PN: HEM-RXL31)

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

The device can also send measurement data to third party applications. Transmission is via an integral FCC compliant Bluetooth Low Energy (BLE) module.

Intended User
Home user

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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-9210T was compared to the predicate HEM-7311– K133379 in the device comparison table below.

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Device Comparison

	Predicate Devices	New Device	Comparison
Model Name:	**HEM-7311**	**HEM-9210T**	**-**
510(k) Number	**K133379**	**---**	**-**
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
Environmental of Use	Home	Home	Identical
Patient Population	Adult	Adult	Identical

Specifications / Features

Specification	**HEM-7311**	**HEM-9210T**	**Comparison**
Measurement method	Cuff oscillometric method	Cuff oscillometric method	Identical
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
Pressure sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	Identical

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Specification	**HEM-7311**	**HEM-9210T**	**Comparison**
Applicable cuff (Arm Circumference)	17-22cm (HEM-CS24) 22-32cm (HEM-CR24) 22-42cm (HEM-RML31)	17-22cm (HEM-CS24) Cleared under K133379 22-42cm (HEM-RML31) Cleared under K133379 42-50cm (HEM-RXL31) (New)	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
Accuracy of pulse rate	Within ±5 % of reading	Within ±5 % of reading	Identical
Inflation method	Automatic by electric pump	Automatic by electric pump	Identical
Deflation method	Automatic pressure release valve	Automatic pressure release valve	Identical
Display	LCD digital display	LCD digital display	Identical
Power Source	4”AA”batteries or AC adapter	4”AA”batteries or AC adapter	Identical
Operating conditions	10 to 40 ℃ 15 to 90 %RH	10 to 40 ℃ 15 to 90 %RH	Identical
Storage conditions	-20 to 60 ℃ 10 to 95 %RH	-20 to 60 ℃ 10 to 95 %RH	Identical
Dimensions (mm)	183 (W) × 230 (D) × 99 (H) mm	107 (W) × 141 (D) × 79 (H) mm	Similar in size. Size is not a factor in function of the device
Weight	Approx. 640g (1 lbs6 5/8 oz) (not including battery)	Approx. 290g (10oz) (not including battery)	Similar weight. Weight is not a factor in function of the device
Irregular Heart beat Feature	Yes	Yes	Identical

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Specification	**HEM-7311**	**HEM-9210T**	**Comparison**
Body movement detection	Yes	Yes	Identical
Hypertension indicator	Yes	No	This feature does not affect fundamental BP measurement function
Average of latest three measurements	Yes	No	This feature does not affect fundamental BP measurement function
Provides an average of 3 measurements	Yes	No	This feature does not affect fundamental BP measurement function
Multiple Users	Yes (2)	No	This feature does not affect fundamental BP measurement function
Bluetooth	No	Yes	This feature does not affect fundamental BP measurement function
Power supply	Regulates power voltage regardless of battery voltage.	Regulates power voltage regardless of battery voltage.	Identical
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
Pressure sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	Identical

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Specification	**HEM-7311**	**HEM-9210T**	**Comparison**
Rapid exhaust valve / Deflation Valve	Active electronic control valve that performs cuff air bleeding and release	Active electronic control valve that performs cuff air bleeding and release	Identical
Inflation source	DC rolling diaphragm pump	DC rolling diaphragm pump	Identical
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	Similar, no memory function
Controls	・ START/STOP Button ・ Date/Time setting Button ・ Up/Down Button ・ User ID Selections Button	・ START/STOP Button	Simplified
Cuff (included with device)	Soft Cuff(HEM-RML31) 22-42cm	Soft Cuff(HEM-RML31) 22-42cm	Identical
Biocompatibility of materials	Surface contact Skin Limited duration of use < 24 hours	Surface contact Skin Limited duration of use < 24 hours	Identical

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Differences Between Other Legally Marketed Predicate Devices:
The Omron HEM-9210T is viewed as substantially equivalent to the predicate device because: The HEM-9210T uses the exact same technology and has identical indications for use. The differences that exist between the devices do not raise new issues 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 HEM-7311 510(k) K133379

Prescriptive – The HEM-9210T and predicate are OTC.

Design and Technology – The HEM-9210T has equivalent design and features when compared to the predicate and has the identical technology to the predicate.

Performance and Specifications – The HEM-9210T has equivalent specifications of performance when compared to the predicate.

Materials –
The HEM-CS24 and HEM-RML31 cuffs are identical to the cuffs cleared in the predicate. The patient contacting materials of the cuffs inclusive of the HEM-RXL31 have been tested in accordance with ISO 10993-1 and FDA Guidance. The tests included Cytotoxicity, Sensitization, and Irritation

Patient Population –
The HEM-9210T and predicate are indicated for adults

Environment of Use – Home**,** Identical to the predicate

Compliance with standards The HEM-9210T and predicate comply with AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 80601-2-30, and ANSI/AAMI/ISO 81060-2.

Differences –
There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

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Performance Testing

Non-clinical Testing

Bench
We have performed bench tests and found that the HEM-9210T met all requirements specifications and standards requirements and was found to be equivalent in comparison to the predicate. Testing includes the following:

- Verification Testing
- Testing for compliance to AAMI ES 60601-1
- Testing for compliance to IEC 60601-1-2,
- Testing for compliance to IEC 60601-1-11
- Testing for compliance to IEC 80601-2-30
- Comparative Testing to the predicate

The results demonstrate that the devices perform as intended are substantially equivalent to the performance of the predicate and in accordance with applicable standards.

Biocompatibility of Materials –
The patient contacting materials of the cuff have been tested in accordance with ISO 10993-1 for Cytotoxicity, Sensitization, and Irritation.

ISO 10993-1 considered the patient contacting as Surface, Skin, Limited duration of use.

Human Factors / Usability
We performed usability with 18 lay users. There were no failures, user errors or near misses.

Clinical Testing Summary:
Testing to insure clinical accuracy of the device in accordance with ANSI/AAMI/ISO 81060-2.
This testing was performed on 92 patients with results showing compliance to the standard.

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