



November 8, 2018

Omron Healthcare, Inc.
% Ron Warren
Senior Director, Regulatory Affairs
Experien Group
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K182166
Trade/Device Name: Wrist Blood Pressure Monitor Model BP4350
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 9, 2018
Received: August 10, 2018

Dear Ron Warren:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shawn W. Forrest -

A

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Digitally signed by Shawn W. Forrest - A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=1300403341,
cn=Shawn W. Forrest - A
Date: 2018.11.08 14:42:46 -05'00'

Enclosure

Indications for Use

510(k) Number (if known)

K182166

Device Name

Wrist Blood Pressure Monitor Model BP4350

Indications for Use (Describe)

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5cm to 21.5cm). 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

510(k) Notification K

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

Omron Healthcare, Inc.
1925 West Field Court
Lake Forest, IL 60045
USA
Phone: 847-247-5626
FAX: 847-680-6269

Contact Person:

Ronald S. Warren
Senior Director, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110
USA
Phone: 408-505-3926
FAX: 408-400-0856

Date Prepared: August 8, 2018

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Wrist Blood Pressure Monitor Model BP4350

Generic/Common Name:

Noninvasive blood pressure measurement system

Classification:

Class II per 21 CFR§870.1130

Product Code:

DXN

510(k) SUMMARY

PREDICATE DEVICE(S) [807.92(a)(3)]

The Wrist Blood Pressure Monitor Model BP4350 is substantially equivalent to the Omron BP652N (HEM-6300-Z) with APS Noninvasive Blood Pressure Measurement System (K142917).

DEVICE DESCRIPTION [807.92(a)(4)]

The Wrist Blood Pressure Monitor Model BP4350 (“BP4350”) is a battery-powered, automatic, noninvasive, wrist-worn blood pressure measuring system intended for over-the-counter (OTC) home use. BP4350 is designed for wrist circumference ranging from 5.3 inches to 8.5 inches (13.5cm to 21.5cm). The systolic and diastolic blood pressures are measured using the oscillometric method, where the cuff is inflated with an integral controllable Piezoelectric pump and deflates via an electric automatic rapid deflation valve. During inflation, the cuff pressure is monitored, and pulse waveform data is extracted. The extracted pulse waveform data is then further analyzed by software which determines pulse rate, as well as systolic and diastolic blood pressure. The cuff can measure pressure range from 0 to 299mmHg, and the pulse rate range from 40 to 180 beats/min.

The device also detects the appearance of irregular heartbeats during the blood pressure measurement process, which is defined as the appearance of two (2) or more heartbeat intervals which differ by greater than 25% from the average heartbeat rhythm. Detection of such irregular rhythms would result in an “irregular heartbeat symbol” displayed along with the blood pressure and pulse rate readings. In addition, a “HIGH” indication appears if the blood pressure recorded is greater than 130/80 based on the AHA/ACC High Blood Pressure Clinical Practice Guideline criterion for Stage 1 Hypertension, published in 2017.

In addition, the device includes an Advanced Positioning Sensor (APS) feature known as the Heart Zone Indicator, which aids the user in determining if the Wrist Cuff is at the correct height in relation to the heart. It makes this determination based on the reading of an accelerometer (integral to the device) to measure the angle of the arm in relation to the table. The APS feature is similar to the predicate device.

The device displays the latest blood pressure reading, while up to 100 readings can be stored in memory. The operation of the device is intended for home use. Functions and other features that are controlled by the end user include applying the wrist cuff to the wrist, powering on/off the system, starting or stopping the blood pressure and pulse measurement cycle, and installing and changing the batteries as needed. As an optional feature, the user can also pair the BP4350 to a smartphone when employing the “Omron connect” app. This app is an optional feature and is only intended to display trend graphs of measured systolic and diastolic blood pressure, and pulse rate. This app does not provide any diagnostic or measurement functions and does not interpret or analyze the data for medical decision making. Unlimited readings can be stored in the app for archiving and review by the user. Aside from this optional app for smartphones, BP4350 does not connect with other collateral devices.

510(k) SUMMARY

INDICATIONS FOR USE [807.92(a)(5)]

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5cm to 21.5cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

The proposed BP4350 has similar technological characteristics as compared to the predicate BP652N device. Both devices are intended for home use and employ the oscillometric method for measuring blood pressure and pulse rate. Both devices have the same cuff pressure range of 0 to 299mmHg and pulse rate range of 40 to 180 beats/min. Both devices are intended for a wrist circumference range of 5.24 – 8.5 inches (13.5 – 21.5cm). The accuracy of pressure reading is ± 3 mmHg for both devices, and accuracy of pulse rate is $\pm 5\%$ in both devices. There are minor differences between BP4350 and BP652N in functional features, such as new hypertension threshold (per new AHA guideline) for the hypertension indicator function, the Morning Averages feature, and the Cuff Wrap Guide. However, these last two features are included on previously cleared Omron blood pressure monitors, Model HEM-780N3 and HEM-6131, and these two devices are identified as reference devices in the Substantial Equivalence summary table below.

SUBSTANTIAL EQUIVALENCE

The proposed Indications for Use for BP4350 is substantially equivalent to the Indications for Use for the predicate device. Comparative testing demonstrated that the proposed device is equivalent to the predicate device with regard to measurement reproducibility of blood pressure and pulse rate in a pulse wave generator test. Minor differences in technological features relate to convenience considerations for home use but do not impact safety or performance of blood pressure or pulse rate measurements. In addition, the differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, BP4350 is substantially equivalent to the predicate BP652N device as described in the Substantial Equivalence Summary, Table 5.1.

510(k) SUMMARY

Table 5.1: Substantial Equivalence Summary Table

	Proposed Device	Primary Predicate Device	Reference Device	Reference Device	SE Assessment to Predicate Device
Model Number	BP4350 (HEM-6232T-Z)	BP652N (HEM-6300-Z)	HEM-780N3	HEM-6131	---
K number	---	K142917	K061822	K131742	---
CFR Classification Class I/II/III	§870.1130 II	§870.1130 II	§870.1130 II	§870.1130 II	Identical
Product Code	DXN	DXN	DXN	DXN	Identical
Indications for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5cm to 21.5cm). 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 with wrist circumference ranging from 5 ¼ inches to 8 1/2 inches (13.5cm to 21.5cm). 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 with arm circumference ranging from 9 inches to 17 inches (22cm to 42cm). 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 with wrist circumference ranging from 5 ¼ inches to 8 1/2 inches (13.5cm to 21.5cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Identical
Environment of Use	Home	Home	Home	Home	Identical
Patient Population	Adults	Adults	Adults	Adults	Identical
Specifications					
Measurement Method / Principal of Operation	Cuff oscillometric method. Identical to both predicates	Cuff oscillometric method. Identical to both predicates	Cuff oscillometric method	Cuff oscillometric method	Identical
Measurement Range	Cuff pressure range 0 to 299mmHg Pulse Rate: 40 to 180 beats/min.	Pressure: 0 to 299mmHg Pulse Rate: 40 to 180 beats/min.	Cuff pressure range 0 to 294mmHg Pulse Rate: 40 to 180 beats/min.	Cuff pressure range 0 to 299mmHg Pulse Rate: 40 to 180 beats/min.	Identical
Pressure Sensor	Semiconductor pressure sensor.	Semiconductor pressure sensor.	Capacitive pressure sensor	Semiconductor pressure sensor.	Identical
Applicable Cuff (Wrist Circumference)	13.5-21.5cm	13.5-21.5cm	22 – 42cm	13.5 – 21.5cm	Identical
Accuracy of Pressure Indicator	Within ±3mmHg	Within ±3mmHg or 2% of reading	Within ±3mmHg or 2% of reading	Within ±3mmHg or 2% of reading	Identical
Accuracy of Pulse Rate Inflation Method	Within ±5% of reading Automatic inflation with piezoelectric pump	Within ±5% of reading Automatic inflation with piezoelectric pump	Within ±5% of reading Automatic inflation with piezoelectric pump	Within ±5% of reading Automatic inflation with piezoelectric pump	Identical
Deflation Method	Automatic rapid deflation valve	Automatic rapid deflation valve	Automatic rapid deflation valve	Automatic rapid deflation valve	Identical
Display	LCD digital display	LCD digital display	LCD digital display	LCD digital display	Identical
Power Source	2 “AAA” batteries	2 “AAA” batteries	4 “AA” batteries	2 “AAA” batteries	Identical
Operating Conditions	10 to 40°C (50 to 104°F) 15 to 90%RH (non-condensing) 800 to 1060hPa	10 to 40°C (50 to 104°F) 15 to 85%RH	10 to 40°C (50 to 104°F) 30 to 85%RH	10 to 40°C (50 to 104°F) 30 to 85%RH	Similar (Slightly changed to comply with IEC60601-1)

510(k) SUMMARY

Table 5.1: Substantial Equivalence Table – Regulatory Information (cont.)

Storage Conditions	-20 to 60°C (-4 to 140°F) 10 to 90%RH (non-condensing)	-20 to 60°C 10 to 95%RH	-20 to 60°C (-4 to 140°F) 10 to 90%RH (non-condensing)	-20 to 60°C (-4 to 140°F) 10 to 95%RH (non-condensing)	Similar (Slightly changed to comply with IEC60601-1)
Dimensions (mm)	91mm (W) × 13.4mm (D) × 63.4mm (H)	89mm (W) × 13mm (D) × 61mm (H)	131mm (W) × 155mm (D) × 84mm (H)	Approx. 78mm (W) x 21mm (D) x 60mm (H) (without the wrist cuff)	Similar, with proposed device having slightly larger dimensions
Weight	Approx. 90g (3.2 oz) (not including battery)	Approx. 80g (2 7/8 oz) (not including battery)	Approx. 420g (14.9 oz) (not including battery)	Approx. 101g (not including battery)	Similar
Features					
Irregular Heart Beat Detection	Yes	Yes	Yes	Yes	Identical
Body Movement Detection	Yes	Yes	Yes	Yes	Identical
Heart Zone Indicator	Yes	Yes (Cleared with the name Advanced Positioning System)	No	Yes	Identical (Exactly same specification for predicate is used for new device N182)
Hypertension Indicator	Yes (Use 130/80 with “High” symbol based on published 2017 AHA guideline)	Yes (Used 135/85 standard with blood pressure level indicator)	No	Yes (Used 135/85 standard with blood pressure level indicator)	Similar (Only threshold is changed)
Morning Averages	Yes	No	Yes	No	Cleared under K061822 (Exactly same specification for K061822 is used for new device)
Cuff Wrap Guide	Yes	No	No	Yes	Cleared under K131742 (HEM-6131) (Specification is identical with K131742)

510(k) SUMMARY

PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing was conducted on the Wrist Blood Pressure Monitor Model BP4350 to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]:

The nonclinical, bench testing included:

- Comparative testing against the predicate BP652N
- Performance verification testing to confirm acceptable performance of device features and functions
- Cleaning verification testing to confirm device retains its performance when cuff is cleaned with household detergents as may be required in home use environment

Other nonclinical safety testing included:

- Biocompatibility testing of patient-contacting materials per ISO 10993-1 requirements
- Evaluation of relevant electrical safety, electromagnetic compatibility and electrostatic discharge requirements per IEC60601 and 80601 requirements and electrostatic discharge testing
- Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Wrist Blood Pressure Monitor Model BP4350 meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Wrist Blood Pressure Monitor Model BP4350 does not raise different questions of safety or effectiveness for measurement of blood pressure and pulse rate in a home use environment when compared to the predicate device.

Clinical Testing Summary [807.92(b)(2)]:

A clinical investigation was conducted with the objective of validating the accuracy of blood pressure measurements by BP4350 based on an oscillometric method as compared to an auscultation method using a calibrated sphygmomanometer by trained medical staff. This study was conducted in accordance with guideline per ANSI/AAMI/ISO 81060-2:2013 *Noninvasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type*. The results demonstrated that BP4350 performed equivalently to the auscultation method and is in conformance with ANSI/AAMI/ISO 81060-2:2013.

CONCLUSIONS [807.92(b)(3)]

Based on the results from the nonclinical and clinical tests performed in support of BP4350, it is concluded that the proposed device is safe and effective, and performs as safely and effectively as the legally marketed BP652N predicate device.

510(k) SUMMARY

SUMMARY

BP4350 and BP652N are designed for the measurement of blood pressure, pulse rate and detection of irregular pulses in adult population for home use. These devices have the same Indications for Use and the performance characteristics related to blood pressure measurement and pulse rate are comparable between the two devices. The minor differences in labeling and technological characteristics between the proposed device and the predicate device have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed BP4350 is substantially equivalent to the predicate device.