DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 21, 2017

Omron Healthcare, Inc.
% Ronald S. Warren
Senior Director, Regulatory Affairs
Experien Group LLC
224 Airport Parkway Suite 250
San Jose, CA 95110 US

Re: K163045
Trade/Device Name: Omron HEM-6400T-Z Wrist Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: January 20, 2017
Received: January 23, 2017

Dear Ronald S. 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. 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 below.

510(k) Number *(if known)*
K163045

Device Name
Omron HEM-6400T-Z Wrist Blood Pressure Monitor

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 6 inches to 8 inches (15.0 cm to 20.5 cm).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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510(k) SUMMARY

510(k) Notification K 163045

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: October 27, 2016

DEVICE INFORMATION

Trade Name:

Omron HEM-6400T-Z Wrist Blood Pressure Monitor

Generic/Common Name:

Noninvasive blood pressure measurement system

Classification:

Class II per 21CFR§870.1130

Product Code:

DXN

510(k) SUMMARY (CONT.)

PREDICATE DEVICE(S)

The Omron HEM-6400T-Z Wrist Blood Pressure Monitor is substantially equivalent to the Omron BP652N (HEM-6300-Z) with APS (K142917).

DEVICE DESCRIPTION

The Omron HEM-6400T-Z Wrist Blood Pressure Monitor is a battery- powered automatic non-invasive blood pressure system intended for home use. The device is powered by a rechargeable lithium-polymer battery. There is no connection to external power. The device inflates a wrist cuff with an integral pump, then deflates the cuff via an electric valve. During inflation, the wrist 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 blood pressure. The systolic and diastolic blood pressures are measured using the oscillometric method. The cuff pressure range is 0 to 299mmHg and the pulse rate range is 30 to 199 beats/min.

HEM-6400T-Z is intended for use in adult patient population with wrist circumference ranging from 6 inches to 8 inches (15.0 cm to 20.5 cm). The device also detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. The device displays the latest blood pressure reading, while up to 100 readings can be stored in memory. In addition, the device includes an Advanced Positioning Sensor (APS) as an aid to the user to determine 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 (to measure the angle of the arm in relation to the table) integral to the device. The APS feature is similar to the predicate device. 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 BP and pulse measurement cycle, and charging the batteries as needed. As an optional feature, the user can also pair the HEM-6400T-Z 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, HEM-6400T-Z does not connect with other collateral devices.

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 6 inches to 8 inches (15.0 cm to 20.5 cm).

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

510(k) SUMMARY (CONT.)

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The proposed HEM-6400T-Z has similar technological characteristics as compared to the predicate BP652N device. Both devices are intended for home use and employ the cuff oscillometric method for measuring blood pressure and pulse rate from the wrist. Both devices have the same cuff pressure range of 0 to 299mmHg. The pulse rate range is similar between the two devices with a range of 30 to 199 beats/min for HEM-6400T-Z and range of 40 to 180 beats/min for the predicate BP652N. The devices accommodate similar sized wrists. HEM-6400T-Z is intended for a wrist circumference of 6 to 8 inches (15.0 cm to 20.5 cm) while the BP652N is intended for a wrist circumference of 5.25 to 8.5 inches (13.5 cm to 21.5 cm). The accuracy of pressure reading is ±3mmHg for both devices, and accuracy of pulse rate is ±5% in both devices. Both devices include detection of irregular heartbeats and give a warning signal with readings. In addition, both devices include an APS as an aid to the user to determine if the wrist cuff is at the correct height in relation to the heart. Both devices utilize a piezoelectric pump for wrist cuff inflation. Both the proposed device and the predicate device employ a semiconductor pressure sensor, and utilize an active electronic control valve that performs cuff air bleeding and release.

There are minor differences between HEM-6400T-Z and BP652N but these do not raise different questions of safety or effectiveness. The HEM-6400T-Z uses a rechargeable lithium-polymer battery as the power source, whereas BP652N uses 2 "AAA" batteries. On the device display, HEM-6400T-Z adds time and date as compared to BP652N display, and the HEM-6400T-Z control buttons have been updated for user convenience. Specifically, the HEM-6400T-Z has a secondary "mini display" on the bottom of the device which also serves as the start/stop button. During the BP measurement, this mini display cycles through a display of systolic pressure, diastolic pressure, and then pulse rate. At the conclusion of the BP measurement, the mini display goes blank and the final results are shown on the main display screen on the top of the device. The BP652N only has a single display screen and start/stop button located on the top of the device. The HEM-6400T-Z wrist cuff main components include an elastomer strap, air bag and metal buckle, while the BP652N wrist cuff main components are a cloth bag, air bag, and hook-and-loop strap (aka Velcro). See Table 5.1 for a summary of the comparison between the proposed device and the predicate device.

510(k) SUMMARY (CONT.)

Table 5.1: Substantial Equivalence Table

Feature	Proposed Device Omron HEM-6400T-Z K163045	Predicate Device Omron BP652N K142917	Analysis of Technological Differences
Classification-Regulation	21 CFR§870.1130, Noninvasive blood pressure measurement system.	21 CFR§870.1130, Noninvasive blood pressure measurement system.	No difference. Proposed device and predicate device have the same medical device classification number
Classification - Product Code	DXN - Noninvasive blood pressure measurement	DXN - Noninvasive blood pressure measurement	No difference. Proposed device and predicate device have the same medical device product code
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 6 inches to 8 inches (15.0 cm to 20.5 cm). 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 1/4 inches to 8 1/2 inches (13.5cut to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	No difference of intended purpose. The proposed indication for use is the same as the cleared indication for use of the predicate device. The wrist circumference is slightly different between the two devices, but this difference does not affect safety or effectiveness.
Environment of Use	Home Use	Home Use	No difference. The proposed device and predicate device have the same environment of use.
Patient Population	Adults	Adults	No difference. Intended for same population.
Contraindications/ Warnings/ Precautions	There are no known contraindications.	There are no known contraindications.	No difference. Proposed device and predicate device have no known contraindications
Single Use	No	No	No difference. Proposed and predicate devices are durable medical equipment intended for multiple uses
Sterility	External contacting device, nonsterile	External contacting device, nonsterile	No difference. Proposed and predicate device are provided nonsterile
Label Information	Labeled for OTC (Home Use)	Labeled for OTC (Home Use)	No difference, Label information provided as required by US medical device regulations for home use.

510(k) SUMMARY (CONT.)

Table 5.1: Substantial Equivalence Table (cont.)

Feature	Proposed Device Omron HEM-6400T-Z K163045	Predicate Device Omron BP652N K142917	Analysis of Technological Differences
Specifications/Features			
Measurement method/Principle of operation	Cuff oscillometric method	Cuff oscillometric method	No difference
Measurement range	Pressure: 0 to 299mmHg Pulse Rate: 30 to 199 beats/min.	Pressure: 0 to 299mmHg Pulse Rate: 40 to 180 beats/min.	This minor difference in pulse rate range does not impact safety and effectiveness of the device.
Pressure senor	Semiconductor pressure sensor	Semiconductor pressure sensor	No difference
Applicable cuff (Wrist Circumference)	15.0 to 20.5cm	13.5 to 21.5cm	This minor difference does not impact safety and effectiveness of the device.
Accuracy of pressure indicator	Within ±3mmHg	Within ±3mmHg or 2% of reading	There is no difference in the accuracy range based on mmHg scale
Accuracy of pulse rate	Within ±5 % of reading	Within ±5 % of reading	No difference
Inflation method	Automatic inflation with piezoelectric pump	Automatic inflation by piezoelectric pump	No difference
Deflation method	Automatic rapid deflation valve	Automatic rapid deflation valve	No difference
Display	Organic electroluminescent display	LCD digital display	Similar. Both devices provide digital display of BP and pulse.
Power source	Rechargeable lithium-polymer battery	Two (2) “AAA” batteries	HEM-6400T-Z includes rechargeable battery for user convenience and reduced environmental impact
Operating conditions	5 to 40 °C (41 to 104 °F) 15 to 85 %RH (non-condensing) 800 to 1060 hPa	10 to 40 °C (50 to 104 °F) 15 to 85 %RH	Similar. HEM-6400T-Z operating conditions specified to comply with IEC60601-1 requirements.
Charging/Data transmission conditions	10 to 35 °C (+50 to 95 °F) 15 to 85 %RH(non-condensing)	NA	HEM-6400T-Z has specific battery charging conditions for recharging lithium-ion battery.
Storage conditions	-20 to 40 °C (-4 to 104 °F) 10 to 90 %RH(non-condensing)	-20 to 60 °C (-4 to 140 °F) 10 to 95 %RH	Similar. HEM-6400T-Z has specific storage conditions since lithium-ion battery requires specific storage conditions.
Transporting conditions	-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	Similar. HEM-6400T-Z has specific transporting conditions since lithium-ion battery requires specific transporting conditions.

510(k) SUMMARY (CONT.)

Table 5.1: Substantial Equivalence Table (cont.)

Feature	Proposed Device Omron HEM-6400T-Z K163045	Predicate Device Omron BP652N K142917	Analysis of Technological Differences
Dimensions (mm)	54 (W) × 63 (D) × 16 (H) mm	89 (W) × 61 (D) × 13 (H) mm	Similar. HEM-6400T-Z has smaller dimensions for added convenience in home use.
Weight	Approx. 110g (3 7/8 oz.) (including batteries)	Approx. 80g (2 7/8 oz.) (not including batteries)	This minor difference does not impact safety and effectiveness of the device.
Irregular Heart Beat Feature	Yes	Yes	No difference
Body movement detection	Yes	Yes	No difference
Hypertension indicator	No	Yes	Hypertension Indicator not included in HEM-6400T-Z. Device not intended to make diagnosis of hypertension. Instruction Manual includes statement that only a physician is qualified to diagnose and treat high blood pressure.
Advanced positioning sensor (APS)	Yes	Yes	No difference
Technology/Features Comparison			
Power supply	Regulates power voltage regardless of battery voltage.	Regulates power voltage regardless of battery voltage.	No difference
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	No difference
Pressure sensor	Semiconductor pressure sensor.	Semiconductor pressure sensor	No difference
Rapid exhaust Valve	Active electronic control valve that performs cuff air bleeding and release	Active electronic control valve that performs cuff air bleeding and release	No difference
Inflation source	Piezoelectric pump	Piezoelectric pump	No difference

510(k) SUMMARY (CONT.)

Table 5.1: Substantial Equivalence Table (cont.)

Feature	Proposed Device Omron HEM-6400T-Z K163045	Predicate Device Omron BP652N K142917	Analysis of Technological Differences
Display	Organic electroluminescent display ・ current cuff pressure ・ systolic blood pressure ・ diastolic blood pressure ・ pulse rate ・ error messages ・ time and date ・ latest 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	Different technology for digital display. Similar information displayed.
Controls	・START/STOP Button ・Connection Button ・Memory ・Home Button	・START/STOP Button ・Date/Time setting Button ・Up/Down Button ・User ID Selections Button	Similar. Minor differences relate to user convenience.
Cuff	Wrist Cuff, Composed of elastomer belt, air bag and metal buckle	Wrist Cuff, Composed of cloth bag, air bag and hook-and-loop fastener	Similar. Difference in method to apply device to wrist was evaluated in usability study and found acceptable.
Materials	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance	No difference

SUBSTANTIAL EQUIVALENCE

The indications for use statement for HEM-6400T-Z is identical to that of the predicate BP652N. Comparison testing demonstrated that the proposed device is equivalent to the predicate device with regard to measurement of blood pressure 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. These minor differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, HEM-6400T-Z is substantially equivalent to the predicate BP652N device.

510(k) SUMMARY (CONT.)

PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing was conducted on HEM-6400T-Z to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Comparative blood pressure and pulse rate testing to the predicate device
- Performance verification testing of HEM-6400T-Z to confirm acceptable performance of device features and functions
- Cleaning verification testing to confirm device retains its performance when cuff is exposed to surfactants as may be experienced in home use environment
- Usability testing with a representative population of study participants in a simulated home use environment

Other nonclinical safety testing included:

- Biocompatibility of patient-contacting materials per ISO 10993-1 requirements
- Electrical safety, electromagnetic compatibility, 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 HEM-6400T-Z meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that HEM-6400T-Z does not raise different questions of safety or effectiveness for measurement of blood pressure and pulse in a home use environment when compared to the predicate device.

Clinical Testing Summary:

A clinical investigation was conducted with the objective of validating the accuracy of blood pressure measurements by HEM-6400T-Z based on an oscillometric method as compared to an auscultation method using a calibrated sphygmomanometer by trained medical staff. The results demonstrated that HEM-6400T-Z performed equivalently to the auscultation method.

Conclusions

Based on the results from the nonclinical and clinical tests performed in support of HEM-6400T-Z, it is concluded that that the proposed device is safe, is effective, and performs at least as safely and effectively as the legally marketed predicate device.

Summary

HEM-6400T-Z 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. Performance characteristics related to BP 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 devices have been evaluated and determined to not raise any different issues of safety or effectiveness. As such, the proposed HEM-6400T-Z is substantially equivalent to the predicate device.