November 9, 2018

Omron Healthcare, Inc.
% Ronald Warren
Vice President, Regulatory Affairs
Experien Group
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K182481
Trade/Device Name: HEM-6410T-ZM 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: September 7, 2018
Received: September 10, 2018

Dear Ronald 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

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: 2018.11.09 11:52:21 -05'00'

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182481

Device Name
HEM-6410T-ZM 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 6.3 inches to 7.5 inches (16.0cm to 19.0cm). 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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510(k) Notification K_____

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: September 07, 2018

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Omron HEM-6410T-ZM Wrist Blood Pressure Monitor

Generic/Common Name:

Noninvasive blood pressure measurement system

Classification:

Class II per 21CFR§870.1130

Product Code:

DXN

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

The Omron HEM-6410T-ZM Wrist Blood Pressure Monitor is substantially equivalent to the Omron HEM-6400T-Z (K163045).

DEVICE DESCRIPTION [807.92(a)(4)]

The Omron HEM-6410T-ZM Wrist Blood Pressure Monitor ("HEM-6410T-ZM") is a battery-powered automatic non-invasive blood pressure system intended for home use. HEM-6410T-ZM is intended for use in adult patient population with wrist circumference ranging from 6.3 inches to 7.5 inches (16.0cm to 19.0cm). The device is powered by a rechargeable lithium-polymer battery. An AC adapter is used for charging the device, but the device cannot be operated while charging. The device wrist cuff inflates using an integral pump, and deflates 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 can measure pressure range from 0 to 299mmHg, and the pulse rate range from 40 to 180 beats/min.

The blood pressure reading is displayed in "red" color if the blood pressure recorded is equal to or greater than 130/80 based on the American Heart Association (AHA)/ American College of Cardiology (ACC) High Blood Pressure Clinical Practice Guideline criterion for Stage 1 Hypertension, published in 2017. The device displays the latest blood pressure reading, while up to 100 readings can be stored in memory. The device also detects the appearance of irregular heartbeats during the blood pressure measurement process. An irregular rhythm 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, the device includes an Advanced Positioning Sensor (APS), known as the Heart Zone Indicator, which aids the user to determine if the wrist cuff is at the correct height in relation to the heart. This determination is based on the reading of an accelerometer (integral to the device) to measure the angle of the arm. The APS feature is similar to that of the predicate device. The operation of the device is intended for home use. Additional 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 (BP) and pulse measurement cycle, and charging the battery as needed. As an optional feature, the user can also pair the HEM-6410T-ZM 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-6410T-ZM does not connect with other collateral devices.

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 6.3 inches to 7.5 inches (16.0cm to 19.0cm).

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)]

This section focuses on the comparative summary information related to the HEM-6410T-ZM and the predicate device, the Omron HEM-6400T-Z (K163045), with regard to product labeling, intended use, anatomical sites, patient population, performance testing, technological characteristics and safety characteristics.

The proposed HEM-6410T-ZM device has the same intended use as the predicate HEM-6400T-Z device. Both devices are intended for home use and employ the cuff oscillometric method for measuring blood pressure and pulse rate from the wrist. Additionally, the proposed HEM-6410T-ZM device has similar technological characteristics as compared to the predicate HEM-6400T-Z device. 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 40 to 180 beats/min for HEM-6410T-ZM and range of 30 to 199 beats/min for the predicate HEM-6400T-Z. The devices accommodate similar sized wrists. HEM-6410T-ZM is intended for a wrist circumference of 6.3 to 7.5 inches (16.0cm to 19.0cm) while the HEM-6400T-Z is intended for a wrist circumference of 6 to 8 inches (15.0cm to 20.5cm). 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. Also, both devices include 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. 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 in technical specifications and features offered in HEM-6410T-ZM as compared to HEM-6400T-Z, as detailed in the following table below. However, these relate primarily to user convenience and simplicity of operation. For example, the predicate HEM-6400-T-Z device does not have the hypertension indicators as the proposed HEM-6410T-ZM device that provides an additional alert to user if the blood pressure recorded is equal to or 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, two contraindications were added to the HEM-6410T-ZM Instruction Manual. Specifically, the HEM-6410T-ZM is contraindicated for use in ambulatory environment, and for use on aircraft. These contraindications were added based on labeling for other Omron blood pressure monitors recently cleared by FDA. Aside from these minor differences, there are no differences in the principle of operation, measurement range, accuracy of pressure measurement, or accuracy of pulse measurement. With regard to safety and technological characteristics, HEM-6410T-ZM does not raise different questions of safety or effectiveness and is substantially equivalent to the predicate HEM-6400T-Z device.

Feature	Proposed Device Omron HEM-6410T-ZM K_____	Predicate Device Omron HEM-6400T-Z K163045	Analysis of Technological Differences
Classification-Regulation	21CFR§870.1130, Noninvasive blood pressure measurement system.	21CFR§870.1130, Noninvasive blood pressure measurement system.	Same
Classification - Product Code	DXN - Noninvasive blood pressure measurement	DXN - Noninvasive blood pressure measurement	Same
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 6.3 to 7.5 inches (16.0cm to 19.0cm). 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 6 inches to 8 inches (15.0cm to 20.5cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Similar Indications for Use. The proposed Indications for Use is the same as the cleared Indications 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	Same
Patient Population	Adults	Adults	Same

Feature	Proposed Device Omron HEM-6410T-ZMK_____	Predicate Device Omron HEM-6400T-Z K163045	Analysis of Technological Differences
Specifications/Features			
Measurement method/Principle of operation	Cuff oscillometric method	Cuff oscillometric method	Same
Measurement range	Pressure: 0 to 299mmHg Pulse Rate: 40 to 180 beats/min.	Pressure: 0 to 299mmHg Pulse Rate: 30 to 199 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	Same
Applicable cuff (Wrist Circumference)	16.0 to 19.0cm	15.0 to 20.5cm	This minor difference does not impact safety and effectiveness of the device.
Accuracy of pressure indicator	Within ±3mmHg	Within ±3mmHg	Same
Accuracy of pulse rate	Within ±5% of reading	Within ±5% of reading	Same
Inflation method	Automatic inflation with piezoelectric pump	Automatic inflation with piezoelectric pump	Same
Deflation method	Automatic rapid deflation valve	Automatic rapid deflation valve	Same
Display	Transflective memory-in-pixel LCD	Organic electroluminescent display	Similar. Both devices provide digital display of BP and pulse.
Power source	Rechargeable lithium-polymer battery	Rechargeable lithium-polymer battery	Same
Operating conditions	5 to 40°C (41 to 104°F) 15 to 85% RH (non-condensing) 800 to 1060hPa	5 to 40°C (41 to104°F) 15 to 85% RH (non-condensing) 800 to 1060hPa	Same
Charging/Data transmission conditions	10 to 35°C (+50 to 95°F) 15 to85% RH (non-condensing)	10 to 35°C (+50 to 95°F) 15 to 85% RH (non-condensing)	Same
Storage conditions	-20 to 40°C (-4 to 104°F) 10 to 90% RH (non-condensing)	-20 to 40°C (-4 to 104°F) 10 to 90% RH (non-condensing)	Same
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 90% RH (non-condensing)	Same

Feature	Proposed Device Omron HEM-6410T-ZM K_____	Predicate Device Omron HEM-6400T-Z K163045	Analysis of Technological Differences
Dimensions (mm)	48 (W) × 48 (D) × 14 (H)	54 (W) × 63 (D) × 16 (H)	The slightly smaller size does not impact safety and effectiveness of the device
Weight	Approx. 115g (4.1oz.) (including batteries)	Approx. 110g (3.9oz.) (including batteries)	This minor difference does not impact safety and effectiveness of the device.
Irregular Heart Beat Feature	Yes	Yes	Same
Body movement detection	Yes	Yes	Same
Hypertension indicator	Yes	No	This minor difference does not impact safety and effectiveness of the device. The display shows reading in red if measurement results (SYS or DIA) exceed the criteria defined by American Heart Association (AHA) 2017 guideline.
Advanced positioning sensor (APS)	Yes	Yes	Same

SUBSTANTIAL EQUIVALENCE

The indications for use statement for HEM-6410T-ZM is similar to that of the predicate HEM-6400T-Z device. 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-6410T-ZM is substantially equivalent to the predicate HEM-6400T-Z device.

PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing was conducted on the HEM-6410T-ZM 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 HEM-6400T-Z device
- 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
- Usability testing to confirm device use in representative home users

Other nonclinical safety testing included:

- Biocompatibility 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
- Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of HEM-6410T-ZM meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that HEM-6410T-ZM 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 [807.92(b)(2)]:

A clinical investigation was conducted with the objective of validating the accuracy of blood pressure measurements by HEM-6410T-ZM 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 guidelines per ANSI/AAMI/ISO 81060-2:2013 *Noninvasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type*. The results demonstrated that HEM-6410T-ZM 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 HEM-6410T-ZM, it is concluded that the proposed device performs as safely and effectively as the legally marketed predicate device.

SUMMARY

The proposed HEM-6410T-ZM device, and the predicate HEM-6400T-Z device are both designed for the measurement of blood pressure (BP), pulse rate and detection of irregular pulses in adult population for home use. These devices have similar indications for use and similar performance characteristics related to BP measurement and pulse rate. 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 HEM-6410T-ZM device is substantially equivalent to the predicate device.