510(k) Notification K190693

GENERAL INFORMATION [807.92(a)(1)]

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

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

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DEVICE INFORMATION [807.92(A)(2)]

Classification:
Class II per 21CFR§870.1130

Product Code:
DXN

Trade Name:
Omron HEM-6410T-ZL Wrist Blood Pressure Monitor

Generic/Common Name:
Noninvasive blood pressure measurement system

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

The Omron HEM-6410T-ZL Wrist Blood Pressure Monitor is substantially equivalent to the Omron HEM-6410T-ZM (K182481).

DEVICE DESCRIPTION [807.92(A)(4)]

The Omron HEM-6410T-ZL Wrist Blood Pressure Monitor ("HEM-6410T-ZL") is a battery-powered, automatic, non-invasive blood pressure system intended for home use. HEM-6410T-ZL is intended for use in adult patient population with wrist circumference ranging from 7.1 inches to 8.5 inches (18.0cm to 21.50cm). 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 identical 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-ZL 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-ZL does not connect with other collateral devices.

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

Aside from change in wrist circumference, the proposed indications for use is the same indications for use as the predicate device HEM-6140T-ZM (K182481) as follows:

> *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 7.1 inches to 8.5 inches (18.0cm to 21.5cm).*
>
> *The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.*

SUBSTANTIAL EQUIVALENCE

The proposed HEM-6410T-ZL device has the same intended use as the predicate HEM-6410T-ZM 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-ZL device has identical technological characteristics as compared to the predicate HEM-6410T-ZM device. Both devices have the same cuff pressure range of 0 to 299mmHg. The pulse rate range is the same for the two devices with a range of 40 to 180 beats/min. 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. Both devices give an error message when body movement is detected during BP measurement. 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. The devices have identical design features and user interface.

There are two (2) minor differences in technical specifications in HEM-6410T-ZL as compared to HEM-6410T-ZM. Both minor design modifications of the HEM-6410T-ZL relate to the addition of a larger sized wrist strap ("Large") to accommodate wrist circumference ranging from 7.1 inches to 8.5 inches (18.0cm to 21.5cm) as a line extension of the previously cleared HEM-6410T-ZM which has a "Medium" sized wrist strap for adults with wrist circumference ranging from 6.3 inches to 7.5 inches (16.0cm to 19.0cm). To accommodate the change in wrist strap size, the proposed device has a slightly larger inflatable cuff and a minor change of the algorithm parameters used to calculate diastolic and systolic blood pressure. The design modifications outlined in this Special 510(k) premarket notification do not affect the intended use, indications for use or alter the fundamental scientific technology of the device as detailed in the comparison table below.

Based on these comparisons and completed testing, the proposed HEM-6410T-ZL device is substantially equivalent to the predicate device with regard to function, intended use, and physical characteristics. The minor differences in the technological characteristics between the devices do not raise different questions of safety or effectiveness. Thus, the proposed HEM-6410T-ZL is substantially equivalent to the predicate device.

Substantial Equivalence Comparison Table:

Feature	Proposed Device Omron HEM-6410T-ZL K190693	Predicate Device Omron HEM-6410T-ZM K182481	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 7.1 to 8.5 inches (18.0cm 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 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.	Minor change to wrist strap size to allow use on larger sized wrists.
Environment of Use	Home Use	Home Use	Same
Patient Population	Adults	Adults	Same
Contraindications/ Warnings/ Precautions	There are two (2) contraindications: The monitor is contraindicated for use in ambulatory environments The monitor is contraindicated in aircraft	There are two (2) contraindications: The monitor is contraindicated for use in ambulatory environments The monitor is contraindicated in aircraft	Same
Single Use	No	No	Same
Sterility	External contacting device, nonsterile	External contacting device, nonsterile	Same
Label Information	Labeled for OTC (Home Use)	Labeled for OTC (Home Use)	Same
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: 40 to 180 beats/min.	Same
Pressure senor	Semiconductor pressure sensor	Semiconductor pressure sensor	Same

Substantial Equivalence Comparison Table (Cont.):

Applicable cuff (Wrist Circumference)	18.0 to 21.5cm	16.0 to 19.0cm	Minor change to wrist strap size to allow use on larger sized wrists. Does not impact safety or 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	Transreflective memory-in-pixel LCD	Transreflective memory-in-pixel LCD	Same
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 to 104°F) 15 to 90% RH (non-condensing) 800 to 1060hPa	Same
Charging/Data transmission conditions	10 to 35°C (+50 to 95°F) 15 to 90% RH (non-condensing)	10 to 35°C (+50 to 95°F) 15 to 90% 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
Dimensions (mm)	Case diameter: 48mm Case thickness: 14mm Band width: 30mm	Case diameter: 48mm Case thickness: 14mm Band width: 30mm	Same
Weight	Approx. 120g (4.2oz.) (including batteries)	Approx. 115g (4.1oz.) (including batteries)	Slightly heavier due to larger strap. 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	Yes	Same
Advanced positioning sensor (APS)	Yes	Yes	Same

Substantial Equivalence Comparison Table (Cont.):

Technology/Features Comparison			
Power supply	Regulates power voltage regardless of battery	Regulates power voltage regardless of battery	Same
Microprocessor	Determines blood pressure and pulse Controls the pump, valve and display Detects switch operations Stores measurement results Manages date and time	Determines blood pressure and pulse Controls the pump, valve and display Detects switch operations Stores measurement results Manages date and time	Same
Pressure sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	Same
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	Same
Deflation valve	No	No	Same
Inflation source	piezoelectric	piezoelectric	Same
Display Type and Parameters	Transreflective memory-in-pixel LCD Current cuff pressure Systolic blood pressure Diastolic blood pressure Pulse rate Error messages Time and date Latest results in the memory	Transreflective memory-in-pixel LCD Current cuff pressure Systolic blood pressure Diastolic blood pressure Pulse rate Error messages Time and date Latest results in the memory	Same
Controls	Start/Stop Button Forward Button Home Button	Start/Stop Button Forward Button Home Button	Same
Cuff	Wrist Cuff, composed of elastomer belt, air bag and metal buckle	Wrist Cuff, composed of elastomer belt, air bag and metal buckle	Only the air bag length is extended to support larger wrist circumference. Materials and structure of the air bag are not changed. The elastomer belt and buckle are the same.
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	Same materials and same manufacturing process.

PERFORMANCE DATA [807.92(b)]

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

All necessary bench testing was conducted on the proposed device to support a determination of substantial equivalence to the predicate device. The same test standards and methods used to support the predicate device were employed for this proposed device. To support the minor changes, additional performance testing, software verification and validation was performed to confirm the minor change in algorithm parameters used to calculate blood pressure resulted in comparable readings as compared to the predicate device.

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

Clinical validation of the HEM-6410T-ZL was conducted using the same methodology and test strategy used for the predicate device. The study assessed the accuracy of blood pressure measurements by HEM-6410T-ZL 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-ZL 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-ZL, it is concluded that the proposed device performs as safely and effectively as the legally marketed predicate device.

SUMMARY

The proposed HEM-6410T-ZL device, and the predicate HEM-6410T-ZM 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 the same indications for use and similar performance characteristics related to BP measurement and pulse rate. The minor differences in wrist strap size and minor software algorithm modifications have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed HEM-6410T-ZL device is substantially equivalent to the predicate device.