March 14, 2019

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

Re: K182579
Trade/Device Name: Omron Model BP7900 Blood Pressure Monitor + EKG
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN, DXH, DPS
Dated: March 13, 2019
Received: March 14, 2019

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,

Jessica E. Paulsen -S

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)*
K182579

Device Name
Omron Model BP7900 Blood Pressure Monitor + EKG

Indications for Use *(Describe)*
The device is intended to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously.
The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population.
The device is intended to record, store, and transfer single-channel electrocardiogram (ECG) rhythms. The device also displays ECG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm (when prescribed or used under the care of a physician). The device is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals. The device has not been tested and it is not intended for pediatric use.

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 K182579

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: March 13, 2019

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Omron Model BP7900 Blood Pressure Monitor + EKG

Generic/Common Name:

Noninvasive blood pressure measurement system, DXN
Telephone electrocardiograph transmitter and receiver, DXH
Electrocardiograph, DPS

Classification:

21CFR §870.1130, Noninvasive blood pressure measurement system, Class II
21 CFR§870.2920, Telephone electrocardiograph transmitter and receiver, Class II
21 CFR§870.2340, Electrocardiograph, Class II

Product Code:

DXN, Noninvasive Blood Pressure Measurement System
DXH, Telephone electrocardiograph transmitter and receiver
DPS, Electrocardiograph

PREDICATE DEVICES [807.92(a)(3)]

The Omron Healthcare, Inc. Omron Model BP7900 Blood Pressure Monitor + EKG is substantially equivalent to the Omron Healthcare, Inc. Model HEM-7311 (K133379) and the AliveCor, Inc. AliveCor Health Monitor (K142743). The proposed BP7900 device utilizes the same ECG analysis algorithm including capabilities to detect the presence of bradycardia and tachycardia as that used in the AliveCor KardiaAI device cleared under K181823. In this regard KardiaAI (K181823) is included as a reference device.

DEVICE DESCRIPTION [807.92(a)(4)]

The Omron Model BP7900 Blood Pressure Monitor + EKG ("BP7900") is a battery-powered automatic, non-invasive blood pressure (BP) and electrocardiography (ECG)[1] measurement system intended for home use.

The BP7900 is intended for use in adult patients with arm circumferences between 17cm and 42cm. The device can be used with two different arm cuffs, the HEM-CS24-B and HEM-RML31-B which are adjustable to ranges of 17-22cm and 22-42cm, respectively. Other than the difference in circumference, the two cuffs function in the same manner.

The device inflates the arm cuff with an integral pump, then deflates the cuff via an electric valve. During inflation, the arm 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 40 to 180 beats/minute. The results of the BP and pulse rate analysis are displayed on the front of the BP7900 for the user. In order to utilize the device, the user must also pair the BP7900 to a smartphone which employs the "Omron connect" app. This app is intended to display trend graphs of measured systolic and diastolic blood pressure, and pulse rate. This app makes use of the cleared AliveCor Heart Monitor algorithm (K142743) to analyze recorded ECGs and identify abnormal heart rhythms based upon the cleared algorithm parameters. Readings can be stored in the app for archiving and review by the user.

In addition to the BP measurement capabilities, the BP7900 also incorporates electrodes capable of gathering ECG data from the user. This can be done either concurrently with BP measurement, or as a separate function. To initiate the ECG, the user places a thumb on each of the right and left electrodes on the top face of the BP7900 and places two or more fingers in contact with the electrodes on the right and left side of the BP7900. The thumb electrodes measure at a rate of 300 samples/second as a single-lead ECG between left and right thumbs. The two remaining finger electrodes on the sides of the BP7900 are used for noise reduction purposes. The single-lead ECG data is transmitted via ultrasonic acoustics to the nearby smartphone with the cleared AliveCor Heart Monitor or OMRON Connect App. These two applications are effectively the same, with the only difference being branding. The cleared app allows the user to view their ECG and the results of analysis using the AliveCor algorithm

[1] Note: ECG is used throughout this submission and technical documentation, however EKG may also be used in labeling and product trade name information for lay persons.

(cleared under K142743) which detects the presence of atrial fibrillation, and normal sinus rhythm.

The proposed BP7900 device utilizes the same ECG analysis algorithm including capabilities to detect the presence of bradycardia and tachycardia as that used in the AliveCor KardiaAI device cleared under K181823. All software V&V testing performed and submitted in this 510(k) utilized this algorithm.

The operation of the device is intended for home use. Functions and other features that are controlled by the end user include: applying the arm cuff to the arm, powering on/off the system, starting or stopping the blood pressure (BP) and pulse measurement cycle, and replacing the batteries as needed. Unlimited readings can be stored in the app for archiving and review by the user.

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

The device is intended to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously.

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population.

The device is intended to record, store, and transfer single-channel electrocardiogram (ECG) rhythms. The device also displays ECG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm (when prescribed or used under the care of a physician). The device is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals. The device has not been tested and it is not intended for pediatric use.

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

The proposed BP7900 combines the intended use of the Omron Healthcare, Inc. Model HEM-7311 ("HEM-7311") (K133379) for the blood pressure function and the AliveCor, Inc. AliveCor Health Monitor (K142743) for the ECG function. Similarly, BP7900 is substantially equivalent to both with regard to intended use, product labeling, anatomical sites, patient population, performance testing, technological characteristics and safety characteristics. With respect to technological characteristics, the BP7900 is equivalent to the HEM-7311 and AliveCor Heart Monitor devices in regard to the BP7900 BP functions and ECG functions, respectively.

In regard to BP function, the proposed BP7900 has the same intended use as its predicate device. Both the BP7900 and the HEM-7311 are intended for home use for the oscillometric measurement of blood pressure and pulse rate utilizing an arm cuff. Both devices have the same cuff pressure range of 0 to 299mmHg and the same pulse rate range of 40 to 180 beats/minute. In both the proposed and predicate device, pulse rate is determined using the same algorithm in which the device measures and records time for several to several dozen pulse waves. When the measured pulse stabilizes during cuff inflation, the software calculates numbers of pulses per minute based on the time and numbers of pulse waves measured. Both devices utilize arm cuffs which cover the same range of circumferences of 17 to 42cm, though the BP7900 has consolidated the size options down to two model sizes of cuff that were employed for the

predicate device: 17-22cm (Model HEM-CS24-B Cuff); and, 22-42cm (Model HEM-RML31-B Cuff)). The predicate device used the same 17-22cm and 22-42cm cuff but also included a mid-range 22-32cm cuff. Both devices also have the same accuracy with respect to pressure indicator and pulse rates and include detection of irregular heartbeats and give a warning signal with readings.

In regard to ECG function, the BP7900 employs the algorithm used for the AliveCor Heart Monitor. The BP7900 does not have an "Irregular Heartbeat Detection" feature which Omron BPMs normally have (estimated from measured BP pulse). Instead, it has an irregular pulse detection feature to identify possible AF, tachycardia, and bradycardia which are estimated from ECG waveforms, not from blood pressure pulse. When BP and ECG are measured simultaneously, the device detects and shows pulse rate from BP pulse (displayed on the device and App), and the heart rate from ECG waveform (displayed on the App only). This is described on Page 17 of the BP7900 Instruction Manual. Thus, for the irregular pulse detection feature (given by AliveCor's algorithm), only the heart rate from the ECG waveform is used.

The BP7900 and both predicate devices are comparable with respect to safety characteristics. The BP7900 and HEM-7311 both have safety features to prevent over-pressurization of the cuff. In addition, all three devices have successfully passed electrical safety, and electromagnetic compatibility and interference requirements per IEC60601 standards. The user-contacting materials of all three devices have also passed biocompatibility testing requirements.

There are other minor differences in the technical specifications and features offered in the BP7900 and HEM-7311. For example, the BP7900 does not have the hypertension indicator that is included in the HEM-7311 which provides an additional alert to the user once the blood pressure measurements exceed the criteria (135/85) established by the JNC 7 guideline. 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. In regard to safety and technological characteristics, the BP7900 does not raise different questions of safety or effectiveness and is substantially equivalent to the HEM-7311.

Both the BP7900 and AliveCor Heart Monitor devices are intended for OTC and Prescription Use and employ the same ECG analysis algorithm to detect the appearance of irregular heartbeats. Both devices also measure a pulse rate of 30 to 300 beats/minute, have very similar data acquisition characteristics (i.e., the same number of ECG channels, resolution, and sample rate), and measure ECG using the same anatomical sites (i.e., left-hand fingers to the right-hand fingers). Additionally, both devices also transmit the gathered data in the same method, utilizing ultrasonic acoustics to communicate with a smartphone.

There are minor differences in the technical specifications and features offered in the BP7900 and the AliveCor Heart Monitor. This includes a slightly different frequency response range for the BP7900 (0.67-40Hz) versus the AliveCor Heart Monitor (0.5-40Hz). The electrodes for the ECG gathering are also slightly different, as the form factor of the BP7900 differs from that of the AliveCor Heart Monitor however both devices still utilize a single lead ECG gathering data from the left-hand fingers to the right-hand fingers. In order to account for potential noise generated by the operation of the BPM, the BP7900 also introduces two additional electrode sensors which help reduce noise interference during the ECG readings. The minor differences in orientation of the sensors and additional noise sensors do not raise different questions of safety or effectiveness. Finally, the proposed BP7900 device utilizes the same ECG analysis algorithm

including capabilities to detect the presence of bradycardia and tachycardia as that used in the AliveCor KardiaAI device cleared under K181823. In this regard KardiaAI (K181823) is included as a reference device. In regard to safety and technological characteristics, the BP7900 does not raise different questions of safety or effectiveness and is substantially equivalent to the AliveCor Heart Monitor.

	Proposed Device Omron BP7900 K182579	Predicate Devices		Reference Device AliveCor KardiaAI (K181823)	SE Assessment to Predicate Devices and Reference Device
		BP measurement Omron Healthcare, Inc. Model HEM-7311 (K133379)	ECG recording AliveCor, Inc. AliveCor Heart Monitor (K142743)		
CFR Classification	21 CFR§870.1130, Noninvasive blood pressure measurement system.	21 CFR§870.1130, Noninvasive blood pressure measurement system.	21 CFR§870.2920, Telephone electrocardiograph transmitter and receiver.	21CFR§870.1425, Programmable diagnostic computer	Same as K133379 Bradycardia and Tachycardia detection same as K181823
Class I/II/III	II	II	II	II	No difference. The proposed device and predicate devices have the same Class.
Product Code	DXN - Noninvasive blood pressure measurement DXH - Telephone electrocardiograph transmitter and receiver DPS - Electrocardiograph	DXN - Noninvasive blood pressure measurement	DXH - Telephone electrocardiograph transmitter and receiver DPS - Electrocardiograph	DQK - Computer, Diagnostic, Programmable DPS - Electrocardiograph	Product codes include those for predicates and reference device.

	Proposed Device Omron BP7900 K182579	Predicate Devices		Reference Device AliveCor KardiaAI (K181823)	SE Assessment to Predicate Devices and Reference Device
		BP measurement Omron Healthcare, Inc. Model HEM-7311 (K133379)	ECG recording AliveCor, Inc. AliveCor Heart Monitor (K142743)		
Indications for Use	The device is intended to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously. The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population. The device is intended to record, store, and transfer single-channel electrocardiogram (ECG) rhythms. The device also displays ECG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm (when prescribed or used under the care of a physician). The device is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals. The device has not been tested and it is not intended for pediatric 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. Environments of Use: Home Patient Population: Adult	The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation and normal sinus rhythm (when prescribed or used under the care of a physician) The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals. The device has not been tested and it is not intended for pediatric use.	KardiaAI is a software analysis library intended to assess ambulatory electrocardiogram (ECG) rhythms from adult subjects. The device supports analyzing data recorded in compatible formats from any ambulatory ECG devices such as event recorders, or other similar devices. The library is intended to be integrated into other device software. The library is not intended for use in life supporting, or sustaining systems, or ECG monitors, or cardiac alarm, or OTC use only devices. KardiaAI provides the following capabilities: ● ECG noise filtering, ● heart rate measurement from ECGs, ● detection of noisy ECGs, and ● ECG rhythm analysis for detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia (when prescribed or used under the care of a physician).	No difference of intended purpose. The proposed indication for use is the same as the cleared indications for use of the predicate devices. The measurement of irregular heartbeats is captured under the ECG rhythm analysis. BP7900 includes reference to detection of bradycardia and tachycardia. BP7900 uses same algorithm for these capabilities at that cleared for the reference device under K181823.

	Proposed Device Omron BP7900 K182579	Predicate Devices		Reference Device AliveCor KardiaAI (K181823)	SE Assessment to Predicate Devices and Reference Device
		BP measurement Omron Healthcare, Inc. Model HEM-7311 (K133379)	ECG recording AliveCor, Inc. AliveCor Heart Monitor (K142743)		
Environment of Use	Home Use (OTC)	Home Use (OTC)	Mobile/active users at rest (ambulatory)	OTC and Prescription Use	OTC use same as predicates. Physician use (for bradycardia and tachycardia detection) same as reference device.
Patient Population	Adults	Adults	Adult (non-pediatric)	Adults	Same as predicates and reference device.
Contraindications/ Warnings/ Precautions	Added contraindications (n=2) against use in ambulatory environments and aircraft.	There are no known contraindications.	There are no known contraindications.	There are no known contraindications.	The BP7900 includes two (2) additional contraindications to be consistent with recent FDA requests received during the review process for Omron's other non-invasive blood pressure monitors. They are not due to technological differences and do not alter the Intended Use of the device.
Single Use	No	No	No	No	Same as predicates and reference device.
Sterility	External contacting device, nonsterile	External contacting device, nonsterile	External contacting device, nonsterile	External contacting device, nonsterile	Same as predicates and reference device.
Label Information	Labeled for both OTC (Home Use) and Rx (Prescription Use)	Labeled for OTC (Home Use)	Labeled for both OTC (Home Use) and Rx (Prescription Use)	Labeled for both OTC (Home Use) and Rx (Prescription Use)	Same as predicates and reference device.

Specifications/Features					
Measurement Method / Principal of Operation	**BP measurement:** Cuff oscillometric method **ECG recording:** User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG	Cuff oscillometric method	User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG	- An interface that provides tools to process and analyze ECGs through various algorithms - The automated proprietary ECG algorithms provide supportive information for ECG diagnosis. The library can be accessed by directly connecting to the KardiaAI's Application Programming Interface	**BP measurement:** Same as HEM-7311. **ECG recording:** Same as Heart Monitor. The minor differences in orientation of the sensors and additional noise sensors do not raise different questions of safety or effectiveness. Bradycardia and Tachycardia detection same as reference device.
Measurement Range	**BP measurement:** Pressure: 0 to 299mmHg Pulse Rate: 40 to 180 beats/min. **ECG recording:** Pulse Rate: 30 to 300 beats/min.	Pressure: 0 to 299mmHg Pulse Rate: 40 to 180 beats/min.	Pulse Rate: 30 to 300 beats/min.	**n/a**	**BP measurement:** Same as HEM-7311. **ECG recording:** Same as Heart Monitor.
Pressure Sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	None	n/a	Same as HEM-7311.
Applicable cuff (Arm Circumference)	17-22cm (HEM-CS24-B) 22-42cm (HEM-RML31-B)	17-22cm (HEM-CS24) 22-32cm (HEM-CR24) 22-42cm (HEM-RML31)	None	n/a	Similar to HEM-7311. Cuff and tubing are identical to HEM-7311 cuffs (HEM-CS24, HEM-RML31) and only the plug shape has changed from HEM-7311 cuffs in order to comply with the ISO standards (ISO 80369-1/-5) for small-bore connector. The diameter of plug and connector are increased in accordance with hazard analysis. This change does not raise different questions of safety or effectiveness.
Accuracy of pressure indicator	Within ±3mmHg or 2% of reading	Within ±3mmHg or 2% of reading	None	n/a	Same as HEM-7311.
Accuracy of pulse rate	Within 5% of reading	Within 5% of reading	Unknown	Unknown	Same as HEM-7311.
Inflation Method	Automatic inflation by electric pump	Automatic inflation by electric pump	None	n/a	Same as HEM-7311.

Deflation Method	Automatic pressure release valve	Automatic pressure release valve	None	n/a	Same as HEM-7311.
Display	LCD digital display on device and Smartphone display	LCD digital display	Smartphone display	n/a	Same as HEM-7311 and Heart Monitor.
Power Source	4 AA" batteries	4 "AA" batteries or AC adapter	1 Lithium Manganese Dioxide Coin Cells	n/a	Proposed device is battery powered. This feature does not affect fundamental BP measurement function nor ECG recordings.
Operating Conditions	10 to 40°C 15 to 90% RH	10 to 40°C 15 to 90% RH	10 to 40°C	n/a	Same as HEM-7311.
Storage Conditions	-20 to 60°C 10 to 95% RH	-20 to 60°C 10 to 95% RH	-20 to 60°C	n/a	Same as HEM-7311.
Dimensions (mm)	231 (W) × 98 (D) × 123 (H) mm	183 (W) × 230 (D) × 99 (H) mm	118 (W) × 62 (D) × 16.5 (H) mm	n/a	Similar. Size is not a factor in function of the device and these differences do not raise different questions of safety or effectiveness.
Weight	Approximately 21oz (600g) (not including batteries)	Approx. 22 5/8oz (640g) (not including battery)	40g	n/a	This minor difference does not impact or raise different question on the safety or effectiveness of the device.
Irregular Heart Beat Detection	Yes ECG detectors (Unreadable and Possible Atrial Fibrillation etc.) by APP refers to this specification.	Yes	Yes ECG detectors (Unreadable and Possible Atrial Fibrillation etc.) by APP refers to this specification.	Yes, includes ECG rhythm analysis for detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia (when prescribed or used under the care of a physician).	Same as Heart Monitor. Bradycardia and Tachycardia detection same as reference device.
Body Movement Detection	Yes, for BP measurement	Yes, for BP measurement	No	n/a	Same as HEM-7311.
Hypertension indicator	No	Yes	No	n/a	This feature does not affect fundamental BP measurement function. As such removal of this feature does not introduce different questions of safety or effectiveness.

Provides an average of 3 measurements	No	Yes	No	n/a	This feature does not affect fundamental BP measurement function. As such removal of this feature does not introduce different questions of safety or effectiveness.
Multiple Users	No	Yes (2)	No	n/a	This feature does not affect fundamental BP measurement function. As such removal of this feature does not introduce different questions of safety or effectiveness.
Communications	**BP measurement:** Bluetooth **ECG recording:** Ultrasonic Acoustics acquired by phone	None	Ultrasonic Acoustics acquired by phone	**n/a**	**BP measurement:** This feature does not affect fundamental BP measurement function. **ECG recording:** Same as Heart Monitor.
Data Acquisition for ECG recording:	Yes	None	Yes	The KardiaAI provides the following capabilities: • ECG noise filtering, • heart rate measurement from ECGs, • detection of noisy ECGs, and • ECG rhythm analysis for detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, and tachycardia (when prescribed or used under the care of a physician).	**ECG recording:** Similar to predicate device (AliveCor Health Monitor). The minor difference in frequency response does not affect fundamental ECG recording function or raise different questions of safety or effectiveness. Bradycardia and tachycardia detection algorithm same as reference device.
Frequency Response	0.67 - 40Hz	-	0.5 - 40Hz		
ECG channels	Single Channel	-	Single Channel		
Resolution	16-bit	-	16-bit		
Sample Rate	300 samples/second	-	300 samples/second		

Memory Capacity	**BP measurement:** 90 BP readings can be stored in the internal memory. **ECG recording:** Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes)	100 sets of BP readings for each user can be stored in the internal memory.	Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes)	**n/a**	**BP measurement:** This minor difference does not impact safety and effectiveness of the device. **ECG recording:** Same as Heart Monitor.
Technology/Features					
Power Supply	Regulates power voltage regardless of battery voltage.	Regulates power voltage regardless of battery voltage.	Regulates power voltage regardless of battery voltage.	n/a	Same as HEM-7311.
Microprocessor	**BP measurement:** ・determines blood pressure and pulse rate ・controls the pump, the valve, and the display ・detects switch operations ・stores measurement results ・manages date and time **ECG recording:** None ECG rhythm is analyzed by AliveCor engine.	・determines blood pressure and pulse rate ・controls the pump, the valve, and the display ・detects switch operations ・stores measurement results ・manages date and time	None (ECG rhythm is analyzed by AliveCor engine)	**n/a**	**BP measurement:** Same as HEM-7311. **ECG recording:** Same as Heart Monitor.
Pressure Sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	None	n/a	Same as HEM-7311.
Rapid Exhaust/Deflation Valve	Active electronic control valve that performs cuff air bleeding and release	Active electronic control valve that performs cuff air bleeding and release	None	n/a	Same as HEM-7311.
Inflation Source	DC rolling diaphragm pump	DC rolling diaphragm pump	None	n/a	Same as HEM-7311.

Display	**BP measurement:** LCD (Liquid Crystal Display) displays; ・current cuff pressure ・systolic blood pressure ・diastolic blood pressure ・pulse rate ・error messages **ECG recording:** Smartphone (App) displays; ・ECG rhythm ・ECG detectors (Normal / Possible Atrial Fibrillation / Bradycardia / Tachycardia Unclassified / Unreadable) ・Past ECG recording in the memory ・Some other user convenient information	LCD (Liquid Crystal Display) displays; ・current cuff pressure ・systolic blood pressure ・diastolic blood pressure ・pulse rate ・error messages ・measurement results in the memory	Smartphone (App) displays; ・ECG rhythm ・ECG detectors (Normal / Possible Atrial Fibrillation / Bradycardia / Tachycardia Unclassified / Unreadable) ・Past ECG recording in the memory ・Some other user convenient information	**n/a**	**BP measurement:** Similar to HEM-7311. **ECG recording:** Same as Heart Monitor.
Controls	・START/STOP Button ・Connection Button	・START/STOP Button ・Date/Time setting Button ・Up/Down Button ・User ID Selections Button	None (When electrode is held by users it starts recording)	**n/a**	**BP measurement:** Similar to HEM-7311. **ECG recording:** Same as Heart Monitor.
Number of ECG Leads	Single lead, 4 electrodes (2 neutral electrodes)	None	Single Lead, 2 electrodes	**n/a**	**ECG recording:** Similar to Heart Monitor.
Anatomical sites	**BP measurement:** Upper arm **ECG recording:** Left hand fingers to right hand fingers	Upper arm	Left hand fingers to right hand fingers	**n/a**	**BP measurement:** Same as HEM-7311. **ECG recording:** Same as Heart Monitor. The minor differences in orientation of the sensors and additional noise sensors do not raise different questions of safety or effectiveness.

User Interface for ECG recording: Primary Lead Data Acquisition Hardware Software interface	Yes Lead I, Left to right Ultrasonic acoustics Universal module Apple iOS-based software	None - - - -	Yes Lead I, Left to right Ultrasonic acoustics iPhone case and Universal module Apple iOS-based software	**n/a**	**ECG recording:** Similar to Heart Monitor. The minor difference does not affect fundamental ECG recording function or raise different questions of safety or effectiveness.
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	Patient contact materials of the cuff have been tested in accordance with ISO 10993 and FDA guidance	n/a	Same as predicate devices.

SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate devices are substantially equivalent to the proposed indications for use for the Blood Pressure Monitor + EKG. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the Blood Pressure Monitor + EKG is substantially equivalent to the predicate devices.

PERFORMANCE DATA [807.92(B)]

All necessary bench and clinical testing was conducted on the Blood Pressure Monitor + EKG to support a determination of substantial equivalence to the predicate devices.

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

The nonclinical, bench testing included:

- Comparative performance testing against both predicate devices;
- Performance verification testing;
- Cleaning verification testing; and
- Usability testing to confirm device use in representative home users.

In addition to the above bench testing, the BP7900 also underwent the following testing:

- 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 the Blood Pressure Monitor + EKG meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Blood Pressure Monitor + EKG does not raise different questions of safety or effectiveness when compared to the predicate devices.

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

Two clinical investigations were conducted with the objective of validating the accuracy of blood pressure measurements. One study employed the HEM-7311 device with the HEM-RML31 Cuff, and the other study used the HEM-7130 device with the HEM-CS24 Cuff. Both of these BPM devices have the same algorithm and hardware components related to BP measurement as are used in the BP7900, and employ the same cuffs used for BP7900. The studies were performed to demonstrate comparability of performance of BP measurement 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 BP7900 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 the BP7900, 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 devices.

SUMMARY

The BP7900 Blood Pressure Monitor + EKG is substantially equivalent to the predicate devices. The software algorithm for bradycardia and tachycardia detection is equivalent to the reference device KardiaAI (K181823). The proposed BP7900 device utilizes the same ECG analysis algorithm including capabilities to detect the presence of bradycardia and tachycardia as that used in the AliveCor KardiaAI device cleared under K181823. In this regard KardiaAI (K181823) is included as a reference device.

The Blood Pressure Monitor + EKG, and the predicate devices are both designed for the measurement of blood pressure, pulse rate, ECG 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, pulse rate and ECG analysis. Further, BP7900 includes bradycardia and tachycardia detection capabilities consistent with the reference device (when prescribed or used under the care of a physician.) The minor differences in labeling and technological characteristics between the proposed device and the predicate devices have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed BP7900 is substantially equivalent to the predicate device.