April 1, 2021

Omron Healthcare, Inc.
% Kit Cariquitan
Chief Regulatory Officer
Experien Group
224 Airport Parkway
Suite 250
San Jose, California 95110

Re: K202228
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, QDA
Dated: February 26, 2021
Received: March 2, 2021

Dear Kit Cariquitan:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K202228

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 the output of ECG analysis including detecting the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm, and others. 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.**

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

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## 510(k) SUMMARY

**510(k) Notification K_____**

### GENERAL INFORMATION [807.92(a)(1)]

**Applicant:**
Omron Healthcare, Inc.
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Lake Forest, IL 60045
USA
Phone: 847-247-5626
Fax: 847-680-6269

**Correspondent:**
Kit Cariquitan
Chief Regulatory Officer
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110
USA

**Date Prepared:** August 06, 2020

### DEVICE INFORMATION [807.92(A)(2)]

**Classification:**
21 CFR 870.1130, Noninvasive blood pressure measurement system

**Product Code:**
DXN, System, Measurement, Blood-Pressure, Non-Invasive
DXH, Transmitters and Receivers, Electrocardiograph, Telephone
DPS, Electrocardiograph
QDA, Electrocardiograph Software for Over-The-Counter Use

**Trade/Proprietary Name:**
Omron Model BP7900 Blood Pressure Monitor + EKG

**Generic/Common Name:**
Noninvasive Blood Pressure Monitor and Electrocardiograph

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

The Omron Healthcare, Inc. Omron Model BP7900 Blood Pressure Monitor + EKG is substantially equivalent to the Omron Healthcare, Inc. Omron Model BP7900 Blood Pressure Monitor + EKG (K182579) and AliveCor, Inc. KardiaMobile System (K191406).

## 510(k) SUMMARY

### 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) 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 software of the AliveCor, Inc. KardiaMobile System (K191406) 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 Kardia App (part of the KardiaMobile System, K191406) or Omron Connect App (Omron functional equivalent). The cleared app, which is incorporated from the KardiaMobile (K191406), allows the user to view their ECG and the results of analysis using the AliveCor's KardiaAI platform (K181823) which detects the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others.

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 archive and review by the user.

## 510(k) SUMMARY

### 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. 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 incorporates a software update to the cleared BP7900 primary predicate device (K182579), with no change in principles of operation, hardware components, or key specifications; to bring the proposed device's onboarding procedure for accessing ECG functionalities in alignment with the secondary predicate, the AliveCor KardiaMobile System (K191406). The proposed device is substantially equivalent to both predicate devices with regard to intended use, product labeling, anatomical sites, patient population, performance testing, technological characteristics, and safety characteristics.

With respect to technological characteristics, there are no differences between the proposed and primary predicate devices with respect to the key functionalities blood pressure measurement, ECG recording, or ECG analysis. The main difference between the devices, which prompted this 510(k) submission, is a change in the onboarding procedure to access the ECG features. The "unlock overread" restriction has been removed for the first use of the product. This change matches the proposed device's first-use onboarding procedure for accessing ECG functionalities with that of the secondary predicate device. Omron has conducted software testing to demonstrate that the updated onboarding procedure, which is identical to that of the secondary predicate device, has been successfully implemented in the updated software. The removal of the unlock overread restriction for first ECG use does not introduce any new risks or significantly modify existing risks, nor does it remove mitigations of risk as compared with the predicate device. This technological difference therefore does not raise different questions of safety or effectiveness from the predicate devices and supports that the proposed device is substantially equivalent to both predicate devices.

Table 1 presents a tabular substantial equivalence comparison between the proposed device and both predicate devices.

## 510(k) SUMMARY

### Table 1: Substantial Equivalence Comparison

| | **Proposed Device: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG** | **Primary Predicate: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG (K182579)** | **Secondary Predicate: AliveCor, Inc. KardiaMobile System (K191406)** | **SE Assessment to Predicate Devices** |
|---|---|---|---|---|
| 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. | Same. Unchanged from the cleared predicate device. |
| Regulatory Class | II | II | II | Same. Unchanged from the cleared predicate device. |
| Product Codes | DXN - Noninvasive blood pressure measurement<br>DXH - Telephone electrocardiograph transmitter and receiver<br>DPS - Electrocardiograph<br>QDA - Electrocardiograph Software for Over-The-Counter Use | DXN - Noninvasive blood pressure measurement<br>DXH - Telephone electrocardiograph transmitter and receiver<br>DPS - Electrocardiograph | DXH - Telephone electrocardiograph transmitter and receiver<br>DPS - Electrocardiograph<br>QDA - Electrocardiograph Software for Over-The-Counter Use | Product codes include those for predicates. |
| Indications for Use | The device is intended to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously.<br>The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population.<br>The device is intended to record, store, and transfer single-channel electrocardiogram (ECG) rhythms. The device also displays ECG rhythms and the output of ECG analysis including detecting the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm, and others. 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 intended to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously.<br>The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population.<br>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 KardiaMobile System is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms.<br>The KardiaMobile System also displays ECG rhythms and output of ECG analysis from AliveCor's KardiaAI platform including detecting the presence of normal sinus rhythm, atrial fibrillation, bradycardia, tachycardia, and others. The KardiaMobile System 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 is not intended for pediatric use. | Similar. The Intended Use of the proposed device is the same as the predicate device.<br>The wording of the Indications for Use statement with respect to ECG analysis has been updated to reflect the updated onboarding procedure which is consistent with that of the secondary predicate device. |
| Environment of Use | Home Use | Home Use | Home Use | Same as both predicate devices. |

## 510(k) SUMMARY

### Table 1: Substantial Equivalence Comparison (Cont.)

| | **Proposed Device: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG** | **Primary Predicate: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG (K182579)** | **Secondary Predicate: AliveCor, Inc. KardiaMobile System (K191406)** | **SE Assessment to Predicate Devices** |
|---|---|---|---|---|
| Type of Use | OTC: blood pressure features and ECG recording, display, and analysis | OTC: blood pressure features and ECG recording<br>Rx: overread unlock restriction for ECG display and analysis features | OTC: ECG recording, display, and analysis | Same as the primary predicate device for blood pressure features and ECG recording. Same as the secondary predicate device for ECG display and analysis.<br>As the "overread unlock" restriction has been removed from the proposed device for the ECG functionalities, as is consistent with the secondary predicate device; the proposed device is no longer indicated as a Rx (prescription use) device. |
| Patient Population | Adults | Adults | Adult (non-pediatric) | Same as both predicate devices. Unchanged from the cleared predicate device. |
| Key Contraindications/ Warnings/Precautions | Contraindicated against use in ambulatory environments and aircraft. | Contraindicated against use in ambulatory environments and aircraft. | There are no known contraindications. | Same as both predicate devices. Unchanged from the cleared predicate device. |
| Single Use | No | No | No | Same as both predicate devices. Unchanged from the cleared predicate device. |
| Sterility | External contacting device, nonsterile | External contacting device, nonsterile | External contacting device, nonsterile | Same as both predicate devices. Unchanged from the cleared predicate device. |
| **Specifications/Features** | | | | |
| Measurement Method / Principal of Operation | **BP measurement:**<br>Cuff oscillometric method<br>**ECG recording:**<br>User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG | **BP measurement:**<br>Cuff oscillometric method<br>**ECG recording:**<br>User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG | User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG | Same as primary predicate. No change from cleared BP7900 device. |

## 510(k) SUMMARY

### Table 1: Substantial Equivalence Comparison (Cont.)

| | **Proposed Device: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG** | **Primary Predicate: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG (K182579)** | **Secondary Predicate: AliveCor, Inc. KardiaMobile System (K191406)** | **SE Assessment to Predicate Devices** |
|---|---|---|---|---|
| Measurement Range | **BP measurement:**<br>Pressure: 0 to 299mmHg<br>Pulse Rate: 40 to 180 beats/min.<br>**ECG recording:**<br>Pulse Rate: 30 to 300 beats/min. | **BP measurement:**<br>Pressure: 0 to 299mmHg<br>Pulse Rate: 40 to 180 beats/min.<br>**ECG recording:**<br>Pulse Rate: 30 to 300 beats/min. | Pulse Rate: 30 to 300 beats/min. | Same as primary predicate. No change from cleared BP7900 device. |
| Pressure Sensor | Semiconductor pressure sensor | Semiconductor pressure sensor | None | Same as primary predicate. No change from cleared BP7900 device. |
| Applicable cuff (Arm Circumference) | 17-22cm (HEM-CS24-B)<br>22-42cm (HEM-RML31-B) | 17-22cm (HEM-CS24-B)<br>22-42cm (HEM-RML31-B) | None | Same as primary predicate. No change from cleared BP7900 device. |
| Accuracy of pressure indicator | Within ±3mmHg or 2% of reading | Within ±3mmHg or 2% of reading | None | Same as primary predicate. No change from cleared BP7900 device. |
| Accuracy of pulse rate | Within 5% of reading | Within 5% of reading | Unknown | Same as primary predicate. No change from cleared BP7900 device. |
| Inflation Method | Automatic inflation by electric pump | Automatic inflation by electric pump | None | Same as primary predicate. No change from cleared BP7900 device. |
| Deflation Method | Automatic pressure release valve | Automatic pressure release valve | None | Same as primary predicate. No change from cleared BP7900 device. |
| Display | LCD digital display on device and Smartphone display | LCD digital display on device and Smartphone display | Smartphone display | Same as primary predicate. No change from cleared BP7900 device. |
| Power Source | 4 AA" batteries | 4 AA" batteries | 1 Lithium Manganese Dioxide Coin Cells | Same as primary predicate. No change from cleared BP7900 device. |
| Operating Conditions | 10 to 40°C<br>15 to 90% RH | 10 to 40°C<br>15 to 90% RH | 10 to 40°C | Same as primary predicate. No change from cleared BP7900 device. |
| Storage Conditions | -20 to 60°C<br>10 to 95% RH | -20 to 60°C<br>10 to 95% RH | -20 to 60°C | Same as primary predicate. No change from cleared BP7900 device. |
| Dimensions (mm) | 231 (W) × 98 (D) × 123 (H) mm | 231 (W) × 98 (D) × 123 (H) mm | 118 (W) × 62 (D) × 16.5 (H) mm | Same as primary predicate. No change from cleared BP7900 device. |
| Weight | Approximately 21oz (600g)<br>(not including batteries) | Approximately 21oz (600g)<br>(not including batteries) | 40g | Same as primary predicate. No change from cleared BP7900 device. |

## 510(k) SUMMARY

### Table 1: Substantial Equivalence Comparison (Cont.)

| | **Proposed Device: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG** | **Primary Predicate: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG (K182579)** | **Secondary Predicate: AliveCor, Inc. KardiaMobile System (K191406)** | **SE Assessment to Predicate Devices** |
|---|---|---|---|---|
| ECG Detectors | Provided by KardiaAI platform (K181823):<br>• Normal Sinus Rhythm<br>• Atrial Fibrillation<br>• Bradycardia<br>• Tachycardia<br>• Unclassified<br>• Unreadable | Provided by KardiaAI platform (K181823):<br>• Normal Sinus Rhythm<br>• Atrial Fibrillation<br>• Bradycardia<br>• Tachycardia<br>• Unclassified<br>• Unreadable | Provided by KardiaAI platform (K181823):<br>• Normal Sinus Rhythm<br>• Atrial Fibrillation<br>• Bradycardia<br>• Tachycardia<br>• Unclassified<br>• Unreadable | Same as both predicate devices with respect to the use of the cleared AliveCor, Inc. KardiaAI (K181823) analysis functionalities.<br>No change from cleared BP7900 device. |
| Body Movement Detection | Yes, for BP measurement | Yes, for BP measurement | No | Same as primary predicate. No change from cleared BP7900 device. |
| Communications | **BP measurement:**<br>Bluetooth<br>**ECG recording:**<br>Ultrasonic Acoustics acquired by phone | **BP measurement:**<br>Bluetooth<br>**ECG recording:**<br>Ultrasonic Acoustics acquired by phone | Ultrasonic Acoustics acquired by phone | Same as primary predicate. No change from cleared BP7900 device. |
| Data Acquisition for ECG recording:<br>Frequency Response<br>ECG channels<br>Resolution<br>Sample Rate | <br>0.67 - 40Hz<br>Single Channel<br>16-bit<br>300 samples/second | <br>0.67 - 40Hz<br>Single Channel<br>16-bit<br>300 samples/second | <br>0.5 - 40Hz<br>Single Channel<br>16-bit<br>300 samples/second | Same as primary predicate. No change from cleared BP7900 device. |
| Memory Capacity | **BP measurement:**<br>90 BP readings can be stored in the internal memory<br>**ECG recording:**<br>Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes) | **BP measurement:**<br>90 BP readings can be stored in the internal memory<br>**ECG recording:**<br>Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes) | Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes) | Same as primary predicate. No change from cleared BP7900 device. |
| **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. | Same as primary predicate. No change from cleared BP7900 device. |

## 510(k) SUMMARY

### Table 1: Substantial Equivalence Comparison (Cont.)

| | Proposed Device: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG | Primary Predicate: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG (K182579) | Secondary Predicate: AliveCor, Inc. KardiaMobile System (K191406) | SE Assessment to Predicate Devices |
|---|---|---|---|---|
| Microprocessor | **BP measurement:**<br>• Determines blood pressure and pulse rate<br>• Controls the pump, the valve, and the display<br>• Detects switch operations<br>• Stores measurement results<br>• Manages date and time<br>**ECG recording:**<br>None. ECG rhythm is analyzed by AliveCor engine. | **BP measurement:**<br>• Determines blood pressure and pulse rate<br>• Controls the pump, the valve, and the display<br>• Detects switch operations<br>• Stores measurement results<br>• Manages date and time<br>**ECG recording:**<br>None. ECG rhythm is analyzed by AliveCor engine. | None<br>(ECG rhythm is analyzed by AliveCor engine) | Same as primary predicate. No change from cleared BP7900 device. |
| Pressure Sensor | Semiconductor pressure sensor | Semiconductor pressure sensor | None | Same as primary predicate. No change from cleared BP7900 device. |
| 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 | Same as primary predicate. No change from cleared BP7900 device. |
| Inflation Source | DC rolling diaphragm pump | DC rolling diaphragm pump | None | Same as primary predicate. No change from cleared BP7900 device. |
| Display | **BP measurement:**<br>LCD (Liquid Crystal Display) displays;<br>• Current cuff pressure<br>• Systolic blood pressure<br>• Diastolic blood pressure<br>• Pulse rate<br>• Error messages<br>**ECG recording:**<br>Smartphone (App) displays;<br>• ECG rhythm<br>• ECG detectors (Normal / Possible Atrial Fibrillation / Bradycardia / Tachycardia Unclassified / Unreadable)<br>• Past ECG recording in the memory<br>• Some other user convenient information | **BP measurement:**<br>LCD displays;<br>• Current cuff pressure<br>• Systolic blood pressure<br>• Diastolic blood pressure<br>• Pulse rate<br>• Error messages<br>**ECG recording:**<br>Smartphone (App) displays;<br>• ECG rhythm<br>• ECG detectors (Normal / Possible Atrial Fibrillation / Bradycardia / Tachycardia Unclassified / Unreadable)<br>• Past ECG recording in the memory<br>• Some other user convenient information | Smartphone (App) displays;<br>• ECG rhythm<br>• ECG detectors (Normal / Possible Atrial Fibrillation / Bradycardia / Tachycardia Unclassified / Unreadable)<br>• Past ECG recording in the memory<br>• Some other user convenient information | **BP measurement:**<br>Same as primary predicate. No change from cleared BP7900 device.<br>**ECG recording:**<br>Same as both predicate devices with respect to types of information displayed. The specific content displayed to the user within the software (e.g., on-screen text and user interface) has been updated from the primary predicate device to be consistent with that of the secondary predicate device. |

## 510(k) SUMMARY

### Table 1: Substantial Equivalence Comparison (Cont.)

| | **Proposed Device: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG** | **Primary Predicate: Omron Healthcare, Inc. Omron BP7900 Blood Pressure Monitor + EKG (K182579)** | **Secondary Predicate: AliveCor, Inc. KardiaMobile System (K191406)** | **SE Assessment to Predicate Devices** |
|---|---|---|---|---|
| Controls | • START/STOP Button<br>• Connection Button | • START/STOP Button<br>• Connection Button | None (When electrode is held by users it starts recording) | Same as primary predicate. No change from cleared BP7900 device. |
| Number of ECG Leads | Single lead, 4 electrodes (2 neutral electrodes) | Single lead, 4 electrodes (2 neutral electrodes) | Single Lead, 2 electrodes | Same as primary predicate. No change from cleared BP7900 device. |
| Anatomical sites | **BP measurement:**<br>Upper arm<br>**ECG recording:**<br>Left hand fingers to right hand fingers | **BP measurement:**<br>Upper arm<br>**ECG recording:**<br>Left hand fingers to right hand fingers | Left hand fingers to right hand fingers | Same as primary predicate. No change from cleared BP7900 device. |
| User Interface for ECG recording:<br>Primary Lead<br>Data Acquisition<br>Hardware<br>Software interface | <br><br>Lead I, Left to right<br>Ultrasonic acoustics<br>Universal module<br>Apple iOS-based or Google Android-based software | <br><br>Lead I, Left to right<br>Ultrasonic acoustics<br>Universal module<br>Apple iOS-based or Google Android-based software | <br><br>Lead I, Left to right<br>Ultrasonic acoustics<br>iPhone case and Universal module<br>Apple iOS-based or Google Android-based software | Same as primary predicate. No change from cleared BP7900 device. |
| 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 | Same as primary predicate. No change from cleared BP7900 device. |

## 510(k) SUMMARY (CONT.)

### SUBSTANTIAL EQUIVALENCE

The proposed Indications for Use for the proposed device, the Omron BP7900 Blood Pressure Monitor + EKG, is substantially equivalent to the Indications for Use for the predicate devices. Any differences in the technological characteristics between the devices do not raise any different questions of safety or effectiveness. Thus, the Omron BP7900 Blood Pressure Monitor + EKG is substantially equivalent to the predicate devices.

### PERFORMANCE DATA [807.92(b)]

All necessary performance testing was conducted on the proposed Omron Model BP7900 Blood Pressure Monitor + EKG to support a determination of substantial equivalence to the predicate device.

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

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 cleared BP7900 primary predicate device were employed for this proposed device. To support the minor changes, additional software verification and validation was performed to confirm the minor change in onboarding procedures were successfully implemented, and that the device continues to perform as intended in accordance with its proposed intended use.

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

No clinical testing was conducted in support of this 510(k) Premarket Notification.

### CONCLUSIONS [807.92(b)(3)]

Based on the results from the nonclinical tests performed in support of the updated BP7900, it is concluded that the proposed device performs at least as safely and effectively as the legally marketed predicate devices.

### SUMMARY

The Omron Model BP7900 Blood Pressure Monitor + EKG is substantially equivalent to the predicate devices.