DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 22, 2016

Omron Healthcare, Inc.
% Ronald Warren
Senior Director, Regulatory Affairs
Experien Group
755 N. Mathilda Ave, Suite 100
Sunnyvale, California 94085

Re: K162092
Trade/Device Name: Evolv Model Bp7000 Upper Arm Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 11, 2016
Received: October 13, 2016

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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162092

Device Name
Evolv Model BP7000 Upper Arm 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 arm circumference ranging from 9 inches to 17 inches (22cm to 42cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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

**FOR FDA USE ONLY**

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

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**OMRON EVOLV MODEL BP7000 UPPER ARM BLOOD PRESSURE MONITOR**
**510(k) SUMMARY**

## 510(k) Notification K162092

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

**Applicant:**

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**Date Prepared: October 7, 2016**

### DEVICE INFORMATION

**Trade Name:**

Evolv Model BP7000 Upper Arm Blood Pressure Monitor

**Generic/Common Name:**

Noninvasive blood pressure measurement system

**Classification:**

Class II per 21CFR870.1130

**Product Code:**

DXN

**OMRON EVOLV MODEL BP7000 UPPER ARM BLOOD PRESSURE MONITOR**
**510(k) SUMMARY**

## PREDICATE DEVICE(S)

The Evolv Model BP7000 Upper Arm Blood Pressure Monitor is substantially equivalent to the Omron HEM-7320 Noninvasive blood pressure measurement system (K133383).

## DEVICE DESCRIPTION

The Evolv Model BP7000 Upper Arm Blood Pressure Monitor ("BP7000") is a battery powered automatic non-invasive blood pressure system intended for home use. The device inflates a cuff with an integral controllable pump, then deflates the cuff via an electric valve. During inflation the 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/min.

BP7000 is intended to be used for arms ranging from 22 to 42cm in circumference. The cuff is not replaceable. The device also detects the appearance of irregular heartbeats during measurement. The device displays the latest blood pressure reading, while up to 100 readings can be stored in memory. 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 upper arm, powering on/off the system, starting or stopping the BP and pulse measurement cycle, and installing and changing the batteries as needed. As an optional feature, the user can also pair the BP7000 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, BP7000 does not connect with other collateral devices.

## INDICATIONS FOR USE

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 inches to 17 inches (22cm to 42cm). 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

The proposed BP7000 has similar technological characteristics as compared to the predicate HEM-7320 device. Both devices are intended for home use and employ the cuff oscillometric method for measuring blood pressure and pulse rate. Both devices have the same cuff pressure range of 0 to 299mmHg and pulse rate range is 40 to 180 beats/min. Both devices are intended for an arm circumference range of 22 to 42mm. The accuracy of pressure reading is ±3mmHg for both devices, and accuracy of pulse rate is ±5% in both devices. There are minor difference between BP7000 and HEM-7320 but these relate to convenience factors for home use. The cuff and display for BP7000 are provided in a one-piece configuration, while there is a separate cuff

and stand-alone desk top display for HEM-7320. BP7000 is battery powered while HEM-7320 is battery powered or AC powered. HEM-7320 has the option to store BP readings for up to two users. BP7000 stores data for one user. BP7000 has slightly smaller dimensions as weighs slightly less than HEM7320. HEM-7320 cuff can be deflated with automatic pressure release or controlled deflation settings. BP7000 cuff is deflated with automatic pressure release only.

### SUBSTANTIAL EQUIVALENCE

The indications for use for the predicate device is substantially equivalent to the proposed indications for use for BP7000. 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. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, BP7000 is substantially equivalent to the predicate HEM-7320 device.

### PERFORMANCE DATA [807.92(b)]

All necessary bench and clinical testing was conducted on BP7000 to support a determination of substantial equivalence to the predicate device.

**Nonclinical Testing Summary:**

The nonclinical, bench testing included:

- Comparative blood pressure and pulse rate testing to the predicate device
- Performance verification testing of BP7000 to confirm acceptable performance of device features and functions
- Cleaning verification testing to confirm device retains its performance when cuff is exposed to surfactants as may be experienced in home use environment
- Usability testing with a representative population of study participants in a simulated home use environment

Other nonclinical safety testing included:

- Biocompatibility of patient-contacting materials per ISO 10993-1 requirements
- Electrical safety, electromagnetic compatibility, and electrostatic discharge testing
- Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of BP7000 meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that BP7000 does not raise new questions of safety or effectiveness for measurement of blood pressure and pulse in a home use environment when compared to the predicate device.

**OMRON EVOLV MODEL BP7000 UPPER ARM BLOOD PRESSURE MONITOR**
**510(k) SUMMARY**

## Clinical Testing Summary:

A clinical investigation was conducted with the objective of validating the accuracy of blood pressure measurements by BP7000 based on an oscillometric method as compared to an auscultation method using a calibrated sphygmomanometer by trained medical staff. The results demonstrated that BP7000 performed equivalently to the auscultation method.

## Conclusions

Based on the results from the nonclinical and clinical tests performed in support of BP7000, it is concluded that that the proposed device is safe, as effective, and performs at least as safely and effectively as the legally marketed predicate device.

### SUMMARY

BP7000 and HEM-7320 are designed for the measurement of blood pressure, pulse rate and detection of irregular pulses in adult population for home use. These devices have the same indications for use. Performance characteristics related to BP measurement and pulse rate are comparable between the two devices. The minor differences in labeling and technological characteristics between the proposed device and the predicate devices have been evaluated and determined to not raise any new issues of safety or effectiveness. As such, the proposed BP7000 is substantially equivalent to the predicate device.