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Food and Drug Administration
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Health & Life Co., Ltd.
Sarah Su
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Re: K160557

Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL158VA
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 7, 2016
Received: June 7, 2016

Dear Sarah Su:

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 yours,



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

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

K160557

Device Name

Full Automatic (NIBP) Blood Pressure Monitor, Model HL158VA

Indications for Use (Describe)

HL158VA automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during inflation. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for adults aged 18 years and older with wrist circumference ranging from 5.3 inches to 7.7 inches (approx. 135 mm to 195 mm) and for home use.

- HL158VA detects the appearance of irregular heartbeats during measurement; an indicated symbol will appear with measuring reading. And the Risk Category Indicator will show the information with the readings on the screen for the user tracking their blood pressure level.

Besides, the device features a built-in "Bluetooth Data Transmission" function, which enables the device automatically transmit measuring results to paired Bluetooth-enabled device. Also, users could simply synchronize the current date and time, and check the battery status of blood pressure monitor by means of DailyChek® application software with the paired Bluetooth-enabled device.

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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PREMARKET NOTIFICATION

510(k) SUMMARY

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____ Date: _____

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL158VA

Common Name: Blood Pressure Monitor

Classification Name: Non-invasive Blood Pressure Measurement System

Classification: Class II, 21 CFR 870.1130

Classification Panel: 74 Cardiovascular

Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

A. Full Automatic (NIBP) Blood Pressure Monitor, Model: HL158BT (K093824)

B. Omron BP652N (HEM-6300-Z) with APS (K142917)

4. Device Description:

HL158VA automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during inflation. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for adults aged 18 years and older with arm circumference ranging from 5.3 inches to 7.7 inches (approx.13.5 cm to 19.5 cm) and for home use.

The device will display a symbol  or **IHB**, to indicate the detection of irregular heartbeat rhythm as defined as a rhythm is more than or less than 25% from the average heartbeat intervals during the measurement. Additionally, after measurement, the Risk Category Indicator function will show the information with the readings on the screen for the user tracking their blood pressure level.

Besides, HL158VA has a built-in Wrist Position Guide. By **holding START/STOP** button, the display will illuminate with different icons that are designed to **guide** you **move your wrist**. Furthermore, the user can use the Bluetooth Data Transmission function, which provides users an optional choice to log, track and store their measurement data. Also synchronize the current date and time, and check the battery status of blood pressure monitor by means of DailyChek[®] application software with the paired Bluetooth-enabled device.

5. Intended Use

HL158VA automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during inflation. All values can be read out in one LCD panel. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults aged 18 years and older with arm circumference ranging from 5.3 inches to 7.7 inches (approx.13.5 cm to 19.5 cm) and for home use.

HL158VA detects the appearance of irregular heartbeats during measurement; an indicated symbol will appear with measuring reading. And the Risk Category Indicator will show the information with the readings on the screen for the user tracking their blood pressure level.

Besides, the device features a built-in "Bluetooth Data Transmission" function, which enables the device automatically transmit measuring results to paired Bluetooth-enabled device. Also, user could simply synchronize the current date and time, and check the battery status of blood pressure monitor by means of DailyChek[®] application software with the paired Bluetooth-enabled device.

6. Comparison of device to predicate device:

A. Product Specification Comparison Table of Subject Device HL158VA, and Predicate Device HL158BT (K093824)

Item	Predicate Device HL158BT (K093824)	Subject Device HL158VA
Method of measurement	Oscillimetric	Same as left
Measurement Type	During deflation	During inflation
Range of measurement	Pressure: 0~ 300mmHg, Pulse 40~199 Beats/minute	Rated Range of Cuff Pressure: 0~ 300mmHg, Rated Range of Determination: 40~280mmHg, Pulse 40~199 Beats/minute
Accuracy	Pressure \pm 3mmHg Pulse \pm 5%	Same as left
Inflation	Automatic	Same as left
Deflation	Automatic (Rapid Exhaust Valve)	Automatic (Passive Exhaust Valve)
Pressure Changed Rate	2-5 mmHg/sec. (from 150mmHg to 90mmHg)	2-5 mmHg/sec. (from 90mmHg to 150mmHg)
Display	Liquid Crystal Digital	Same as left
Power Supply	2 "AAA (1.5V)" Alkaline Batteries	2 "AAA (LR03) (1.5V)" Alkaline Batteries
Storage/	- 20°C ~ + 70°C ,	- 25°C ~ + 70°C

Transportation Environment	(- 4°F ~ +158°F), ≤ 90% R.H.	(- 13°F ~ +158°F), ≤ 93% R.H.
Operating Environment	10°C ~ 40°C , (50°F ~ 104°F), 15% ~ 90% R.H.	5°C ~ 40°C (41°F ~ 104°F), 15% ~ 93% R.H. 700~1060 hPa
Material	ABS housing and rubber keys	ABS housing and ABS keys
Sets of memory	2*60 , total 120	2*120, total 240
Number of Push Button	7 keys (Start/Stop, M(Memory) ,Date/Time (🕒), Set (+) , User(👤) ,Language, Talking Mode button)	6 keys (Start/Stop, M(Memory) ,Date/Time (🕒), Set (+) , User(👤) ,Bluetooth button (📶))
Storage pouch	Yes (Storage Case)	Yes (Storage Pouch)
Cuff size	Wrist circumference approx. 135 ~ 195 mm (Approx. 5.3~7.7 inches)	Same as left
Unit Weight (excluding batteries)	Approx. 136 ± 5 g	Approx. 128 ± 10 g
Risk Category Indicator	Yes	Same as left
Irregular Heartbeat Detector	Yes	Same as left
Data Link Function	Yes (Via USB cable)	Yes (Via Bluetooth)
Talking Function	Yes	No
Wrist Position Guide	No	Yes

Changes from the predicate devices HL158BT (K093824):

- * Modifying the measurement type from “during deflation” into “during inflation”.
- * Changing the memory of 120 (2*60, total 120) to 240 (2*120, total 240).
- * Changing the 7 keys to the 6 keys.
- * Modifying the Data Link Function from USB into Bluetooth Data Transmission Function.
- * Removing the Talking Function.
- * Adding the Wrist Position Guide Function.

These additional features have been verified and validated and do not affect the safety and effectiveness of subject device HL158VA. For the product feature of Wrist Position Guide, was compared with the other predicate device OMRON BP652N. Please refer to **Section 12. Substantial Equivalence Discussion** for detail information.

7. Discussion of Clinical Tests Performed:

HL158VA is compliant to the standard of ISO 81060-2: Second Edition 2013-05-01 Non-invasive sphygmomanometers- Part 2: Clinical validation of automated measurement type. The results of this clinical investigation show that the required limits for mean difference and standard deviation are fulfilled by the subject device HL158VA in the group of 100 subjects with qualified distribution. Thus, all the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

The subject device was tested to evaluate its safety and effectiveness, including the followings:

- a. **EMC Test:** IEC 60601-1-2 Edition 3:2007-03, Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Tests
- b. **Radio Frequency Wireless Test:**
-ETSI EN 300 328, Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques;

- Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
- ETSI EN 301 489-1, Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
 - ETSI EN 301 489-17, Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
- c. **Safety Test:**
- IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
 - IEC 60601-1-11:2010, Medical electrical equipment-Part 1-11: General Requirement for basic safety and essential performance– Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment
- d. **FCC Test:**
- FCC 47 CFR Part 15, Subpart B & FCC 47 CFR Part 15, Subpart C
- e. **Biocompatibility Test:**
- ISO 10993-1:2009, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
 - ISO 10993-5:2009, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity
 - ISO 10993-10:2010, Third Edition Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
- f. **Reliability Test:**
- IEC 80601-2-30 Edition1.1 2013-07 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- g. **Risk Assessment:** ISO 14971:2007 Second Edition, Medical devices - Application of risk management to medical devices

h. Software Verification and Validation:

-IEC 62304 Ed.1.1 (2015), Medical device software - Software life cycle processes,

-IEC 60601-1-4 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems, edition 1.1.

i. Usability Validation:

-IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices

-IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

9. Conclusions:

The subject device was tested and fulfilled the requirements of those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate device.