



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 7, 2016

Health & Life Co., Ltd.
Sarah Su
Director
9F, No. 186, Jian Yi Road
Zhonghe District, New Taipei City, TW 23553 Taiwan

Re: K153214

Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 3, 2015
Received: November 5, 2015

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153214

Device Name

Full Automatic (NIBP) Blood Pressure Monitor, Model HL858DI

Indications for Use (Describe)

HL858DI 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 9 inches to 17 inches (approx.23 cm to 43 cm) and for home use.

HL858DI 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.

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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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: NOV 03 2015

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858DI

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):

Full Automatic (NIBP) Blood Pressure Monitor, Model: HL858CB (K142968)

4. Device Description:

HL858DI 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 9 inches to 17 inches (approx.23 cm to 43 cm) and for home use.

The device will display a symbol ( or **IRREG**), 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.

5. Intended Use

HL858DI 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 9 inches to 17 inches (approx.23 cm to 43 cm) and for home use.

HL858DI 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.

6. Comparison of device to predicate device:

Product Specification Comparison Table of Subject Device HL858DI, and Predicate Device HL858CB (K142968)

Item	Predicate Device HL858CB (K142968)	Subject Device HL858DI
Method of measurement	Oscillimetric	Same as left
Measurement	During deflation	During inflation

Type		
Range of measurement	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute	Same as left
Accuracy	Pressure \pm 3mmHg Pulse \pm 5%	Same as left
Pressure Changed Rate	2~5mmHg/sec.	Same as left
Exhaust	Automatic exhaust valve	Same as left
Display	Liquid Crystal Digital	Same as left
Power Supply	6V 1A, 4 \times AA/1.5V (LR6) Alkaline batteries, or AC adapter (optional)	Same as left
Storage/ Transportation Environment	- 25°C ~ + 70°C (- 13°F ~ +158°F), \leq 93% R.H.	Same as left
Operating Environment	5°C ~ 40°C (41°F~104°F), 15% ~ 93% R.H.	Same as left
Material	ABS housing and ABS keys	Same as left
Sets of memory	2*120, total 240	2*60,total 120
Number of Push Button	7 + 2 switch control (Triple-Check (Multi-Read), Rest Assure)	5 key control
Storage pouch	Yes	Same as left
Cuff size	Arm circumference approx. 23~43cm / 9~17 inch (Universal cuff)	Same as left
Unit Weight	Approx. 393 \pm 10g (Excluding cuff and Batteries)	Approx. 310 \pm 10g (Excluding cuff and Batteries)

Risk Category Indicator	Yes	Same as left
Irregular Heartbeat Detector	Yes	Same as left
Triple-Check (Multi-Read) Function	Yes	No
Rest Assure Function	Yes	No
Data Link function	Yes (Via Bluetooth)	No

Changes from the predicate devices HL858CB (K142968):

- * Modifying the measurement type from “during deflation” into “during inflation”.
- * Changing the memory of 240 (2*120, total 240) to 120 (2*60, total 120).
- * Changing the 7 key & 2 switch control to the 5 key control.
- * Changing the Unit Weight from Approx. $393 \pm 10\text{g}$ to Approx. $310 \pm 10\text{g}$.
- * Removing the Triple-Check (Multi-Read) Function, Rest Assure Function and Bluetooth Data Transmission Function.

These features has been verified and validated and do not affect the safety and effectiveness of subject device HL858DI. Please refer to **Section 12. Substantial Equivalence Discussion** for detail information.

7. Discussion of Clinical Tests Performed:

HL858DI 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 HL858DI in the group of 105 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. **Safety Test:**
 - IEC 60601-1:2005, 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
- c. **FCC Test:**
 - FCC 47 CFR Part 15, Subpart B
- d. **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
- e. **Reliability Test:**
 - IEC 80601-2-30 Edition 1.1 2013-07 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
- f. **Risk Assessment:** ISO 14971:2007 Second Edition, Medical devices - Application of risk management to medical devices
- g. **Software Verification and Validation:**
 - IEC 62304 Ed.1.0 (2006), 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

h. Usability Validation:

-IEC 62366-1:2015 Medical devices - 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.