August 10, 2021

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

Re: K142968
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

Dear Sarah Su:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 19, 2014. Specifically, FDA is updating this SE Letter as an administrative correction for an incorrect 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact LCDR Stephen Browning, OHT2: Office of Cardiovascular Devices, (240) 402-5241, stephen.browning@fda.hhs.gov.

Sincerely,

Stephen C. Browning -S

LCDR 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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 19, 2014

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

Re: K142968
Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858CB
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 15, 2014
Received: October 20, 2014

Dear Ms. 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,

Melissa A. Torres -S

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

Enclosure

510(k) Number (if known): __K142968_____

Device Name: __ Full Automatic (NIBP) Blood Pressure Monitor, Model HL858CB____

Indications For Use:

HL858CB automatically measuers human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. 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.

HL858CB detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring reading. And the device features a built-in "Bluetooth Data Transmission" function, which enables the device automatically transmit measuring results to paired Bluetooth device.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR **Over-The-Counter Use** __X__

(Per 21 CFR 801.109)

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: K142968 Date: _____

1. Submitter:

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Contact person: Sarah Su/ Regulatory Affairs Dept.
E-mail: sarah.su@hlmt.com.tw
Tel: 886-2-8227-1300 ext.1201
Fax: 886-2-8227-1301

2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858CB
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: HL858CA (K131121)
B. Full Automatic (NIBP) Blood Pressure Monitor**,** Model: HL888HD (K113238)

4. Device Description:

HL858CB automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. 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 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, When Triple Check mode is turned on by user, the symbol (3 MULTI-READ) will display on the LCD. Then press Start/Stop button the device will take three consecutive measurements automatically at 1 minute intervals. After measurements are completed, LCD will display the average values of the three measurements. And this device is designed with Rest Assure function as a countdown timer to help user in relax state for 5 minutes before taking measurement. Furthermore, the user can use the Bluetooth Data Transmission function, which provides users an optional choice to log, track and store their measurement data.

5. Intended Use

HL858CB automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method. 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.

HL858CB detects the appearance of irregular heartbeats during measurement; an indicated symbol will appear with measuring reading. And the device features a built-in "Bluetooth Data Transmission" function, which enables the device automatically transmit measuring results to paired Bluetooth device.

6. Comparison of device to predicate device:

Product Specification Comparison Table of Subject Device HL858CB, and Predicate Device HL858CA(K131121)

Item	Predicate Device HL858CA (K131121)	Subject Device HL858CB
Method of measurement	Oscillimetric	Same as left
Range of measurement	Pressure 0- 300mmHg, Pulse 40-199 Beats/minute	Same as left
Accuracy	Pressure ± 3mmHg Pulse ± 5%	Same as left
Inflation	Automatic inflation (Air pump)	Same as left
Deflation	Automatic air release control valve	Same as left
Exhaust	Automatic exhaust valve	Same as left
Display	Liquid Crystal Digital	Same as left
Power Supply	6V 1A, 4 × AA/1.5V (LR6) Alkaline batteries, or AC adapter (optional)	Same as left
Storage/ Transportation Environment	- 25℃ ~ + 70℃ (- 13℉~ +158℉), ≦ 93% R.H.	Same as left
Operating	5℃ ~ 40℃ (41℉~104℉),	Same as left

Environment	15% ~ 93% R.H.	
Material	ABS housing and ABS keys	Same as left
Sets of memory	2*120, total 240	Same as left
Number of Push Button	7 + 2 switch control (Triple check, Rest assure)	Same as left
Storage pouch	Yes	Same as left
Cuff size	Arm circumference approx. 23~33 cm /9~13 inches(Normal cuff) 33~43cm/13~17 inches(Large cuff)	Arm circumference approx. 23~43cm / 9~17 inch (Universal cuff)
Unit Weight	Approx. 393 ± 10g (Excluding cuff and Batteries)	Same as left
Risk Category Indicator	Yes	Same as left
Irregular Heartbeat Detector	Yes	Same as left
Data Link function	Yes (Via USB cable)	Yes (Via Bluetooth)

Changes from the predicate devices HL858CA (K131121):

* Changing the cuff size from Normal cuff (9~13 inches/23-33cm) and Large cuff (13~17 inches/33-43cm) to Universal cuff (9~17 inches/23~43cm).
* Modifying the Data Link Function from USB into Bluetooth Data Transmission Function.

These additional feature has been verified and validated and do not affect the safety and effectiveness of subject device HL858CB.

For the product feature of Bluetooth data transmission, was compared with the other our own predicate device HL888HD (K113238).Please refer to **Section 12. Substantial Equivalence Discussion** for detail information.

7. Discussion of Clinical Tests Performed:

HL858CB is compliant to the standard of ISO 81060-2: First Edition 2009-05-01 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 HL858CB in the group of 90 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 are 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, 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 electricalequipment-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.1.0 (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

i. **Usability Validation**:

-IEC 62366:2007 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.