June 12, 2020

Health & Life Co., Ltd
Simon Lee
RA/QA Div. Deputy Manager
9F, No. 186 Jian Yi Road,
Zhonghe District, New Taipei City, 23553
Taiwan

Re: K200521
Trade/Device Name: Full Automatic(NIBP) Blood Pressure Monitor, Model HL858CP
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 14, 2020
Received: May 15, 2020

Dear Simon Lee:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200521

Device Name
Full Automatic (NIBP) Blood Pressure Monitor, Model HL858CP

Indications for Use *(Describe)*

HL858CP 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 22 inches (approx.23 cm to 56 cm) and for home use.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected in pre-eclampsia condition.

HL858CP 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.

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 HL858CP
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: HL858CL (K190507)
B. Microlife Upper Arm Automatic Digital Blood Pressure Monitor**,** Model: BP3MW1-4B (K153077)

4. Device Description:

HL858CP 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 22 inches (approx.23 cm to 56 cm) and for home use. The device can accurately measure blood pressure in pregnant patients including those with known or suspected in pre-eclampsia condition.

The device will display a symbol  , 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 (

) 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.

HL858CP is equipped with Bluetooth Data Transmission function, which can electronic transfer the measured data of HL858CP to the paired Bluetooth-enabled device. The transferable measured data includes Systolic, Diastolic, and Pulse. The Bluetooth Data Transmission is without controlling or altering the functions or parameters of HL858CP and Paired Bluetooth-enabled device. In addition, the Bluetooth Data Transmission function could transfer the battery status of HL858CP to the Paired Bluetooth-enabled device without any controlling or altering on both devices.

Besides, Bluetooth Data Transmission function could provide Date/Time synchronization for HL858CP, which simply help users set Time/ Date information. It will help users prevent from entering incorrect time information.

5. Intended Use

HL858CP 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 22 inches (approx.23 cm to 56 cm) and for home use.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected in pre-eclampsia condition.

HL858CP 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.

6. Comparison of device to predicate device:

Product Specification Comparison Table of Subject Device HL858CP, and Predicate Device HL858CL (K190507)

Item	Predicate Device HL858CL (K190507)	Subject Device HL858CP
Method of measurement	Oscillimetric	Same as left
Measurement Type	During inflation	Same as left
Range of measurement	Pressure 0- 300mmHg, Rated Range of Determination: 40~280mmHg, Pulse 40-199 Beats/minute	Same as left
Accuracy	Pressure ± 3mmHg Pulse ± 5%	Same as left
Pressure Changed Rate	2~5mmHg/sec. (from 90mmHg to 150mmHg)	Same as left
Display	Liquid Crystal Digital	Same as left

Power Supply	6V 1A, 4 × AA/1.5V (LR6) Alkaline batteries, or AC Adapter (Model: SINPRO, HPU15-102 Input: 100-240V AC 47-63Hz / Output: 5.99V, DC, 2A)	Same as left
Storage/ Transportation Environment	- 25℃ ~ + 60℃ (- 13℉~ +140℉), ≦ 93% R.H.	- 25℃ ~ + 50℃ (- 13℉~ +122℉), ≦ 93% R.H.
Operating Environment	5℃ ~ 40℃ (41℉~104℉), 15% ~ 93% R.H. 700~1060hPa	Same as left
Material	ABS housing and ABS keys	Same as left
Sets of memory	2*120, total 240	Same as left
Number of Push Button	6+1 switch control (Start/Stop, Memory (M), User Select, Bluetooth ( ), Date/Time ( ), AM/PM button; Triple Check slider)	Same as left
Storage pouch	No	Same as left
Cuff size	Arm circumference approx. 23-43 cm / approx.9~17 inches(Universal Cuff) 43 ~ 56 cm / approx.17 ~ 22 inch(Extra Large Cuff)	Same as left
Unit Weight	Approx. 330 ± 5g (Excluding cuff and Batteries)	Same as left
Unit Dimensions	118×163.8×48mm (L×W×H)	Same as left
Risk Category Indicator	Yes (Risk Category Indicator, Five Levels)	Same as left
Irregular Heartbeat Detector	Yes (Irregular Heartbeat Detection)	Same as left

Triple-Check (Multi-Read) Function	Yes	Same as left
Bluetooth Data Transmission	1. Measurement Data Transmission 2. Date/Time Synchronization 3. Battery Status Check	Same as left
Battery Life	≥ 250 times	Same as left
Intended patients population (Pregnant Accuracy)	No	Yes
Error symbol	EE / E1 / E2 / E3 / E4 / Excessive Body Motion Detector	Same as left
Accessories	Arm cuff with tube: 23 ~ 43 cm / approx.9 ~ 17 inches (Universal cuff), 43 ~ 56 cm / approx.17 ~ 22 inches (Extra Large cuff), 4AA/1.5V (LR6) alkaline batteries, 5.99V DC AC Adaptor, instruction manual, gift box.	Same as left

Changes from the predicate devices HL858CL (K190507):

* Add intended population for pregnant accuracy.
* Revise the upper temperature limit of Storage/ Transportation Environment.

These features have been verified and validated and do not affect the safety and effectiveness of subject device HL858CP. As for the newly added pregnant patient population (including those with known or suspected in pre-eclampsia condition) to the subject device HL858CP, was compared with the other predicate device Microlife BP3MW1-4B (K153077). Please refer to **Section 12. Substantial Equivalence Discussion** for detail information. In addition, the clinical investigation record please refer to **Section 20. Performance Testing- Clinical.**

7. Discussion of Clinical Tests Performed:

HL858CP, which includes the Universal cuff and Extra Large cuff, 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 HL858CP 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.

The subject device HL858CP featured the pregnancy accuracy which intended population is the same as the predicate device Microlife Upper Arm Automatic Digital Blood Pressure Monitor (K153077). In addition, the clinical test result of HL858CP meets criteria of ISO 81060-2:2013 and proves the safety and effectiveness of pregnancy accuracy performed as well as the predicate device Microlife Upper Arm Automatic Digital Blood Pressure Monitor (K153077).

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 4:2014, 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 60601-1-11:2015, 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, C

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 2 2018-03 Medical electricalequipment-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.1.1:2006+A1:2015, 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

h. **Usability Validation:**

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

-IEC 60601-1-6:2013 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 has concluded that the subject device is substantially equivalent to the predicate device.