September 8, 2021

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

Re: K211127
Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858DM
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 6, 2021
Received: August 9, 2021

Dear Peggy 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. 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211127

Device Name
Full Automatic (NIBP) Blood Pressure Monitor, Model HL858DM

Indications for Use *(Describe)*
This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate.The measurement position is at human being's arm.
All values can be read out in the LCD panel. Measurement position is at human being's upper arm. The intended user of this over-the-counter device is adults aged 18 years and older with arm circumference ranging from 9 inches to 17 inches (approx.23 cm to 43 cm) for home use.
HL858DM features BP Category Indicator that will show the information with the readings on the screen for the user tracking their blood pressure level.
HL858DM is equipped with an Advanced IHB detection feature to collect and analyze pulses. If the specific irregular heartbeats are detected and it may affect blood pressure reading with deviation, the device will give the user a warning signal. The feature can inform the user that the measured blood pressure reading may be inaccurate once the specific irregular heartbeats are detected.
Besides, the device features a built-in "Bluetooth 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.

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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: K211127 Date: AUG 06 2021

1. Submitter:

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2. Name of the Device:

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858DM
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: HL858DK (K180240)

4. Device Description:

HL858DM 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 has the Risk Category Indicator, Irregular Heartbeat Detector, Bluetooth data transmission functions.

When the symbol Advanced IHB appears on screen indicates the specific heartbeat irregularity was detected during measurement.

Additionally, after measurement, the BP Category Indicator feature will show the information with the readings on the screen for the user tracking their blood pressure level.

Besides, HL858DM featured with an IHB feature can identify the specific irregular heartbeats that may cause deviated blood pressure reading.

5. Intended Use

This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate.
The measurement position is at human being's arm.
All values can be read out in the LCD panel. Measurement position is at human being's upper arm. The intended user of this over-the-counter device is adults aged 18 years and older with arm circumference ranging from 9 inches to 17 inches (approx.23 cm to 43 cm) for home use.
HL858DM features BP Category Indicator that will show the information with the readings on the screen for the user tracking their blood pressure level.
HL858DM is equipped with an Advanced IHB detection feature to collect and analyze pulses. If the specific irregular heartbeats are detected and it may affect blood pressure reading with deviation, the device will give the user a warning signal. The feature can inform the user that the measured blood pressure reading may be inaccurate once the specific irregular heartbeats are detected.

Besides, the device features a built-in "Bluetooth 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 HL858DM, and Predicate Device HL858DK (K180240)

Item	Predicate Device HL858DK (K180240)	Subject Device HL858DM
Method of measurement	Oscillimetric	Same as left
Measurement Type	During inflation	During inflation
Range of measurement	Pressure 0- 300mmHg, 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	4 × AAA/1.5V (LR03) 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 °C ~ 60 °C (- 13 °F~ 158 °F), ≦ 93% R.H.	Same as left
Operating Environment	5 °C ~ 40 °C (41 °F~104 °F), 15% ~ 93% R.H.	Same as left

	700~1060hPa	
Material	ABS housing and ABS keys	Same as left
Sets of memory	3*40,total 120	Same as left
Number of Push Button	5 keys control (Start/Stop, Memory, Up, Down, Time ( ) button)	Same as left
Storage pouch	Yes	Same as left
Cuff size	Arm circumference approx. 23~43cm / 9~17 inch (Universal cuff)	Same as left
Unit Weight	Approx. 320 ± 5g (Excluding cuff and Batteries)	Same as left
Risk/BP Category Indicator	Yes (BP Category Indicator, Six Levels)	Same as left
Irregular Heartbeat Detector	Yes	Same as left
Bluetooth Data Transmission	No	1. Measurement Data Transmission 2. Date/Time Synchronization 3. Battery Status Check

Changes from the predicate devices HL858DK (K180240):

- Add Data Link Function (Bluetooth Data Transmission)

  The subject device HL858DM adds Bluetooth technology function. It provides users an optional choice to log, track and store their measurement data.

  This feature doesn't directly affect the safety and effectiveness of blood pressure measurement. Relevant evaluations such as software verification and validation, risk management activities and usability engineering validation were performed accordingly, and the results show that the Bluetooth Data Transmission function of

the subject device HL858DM could operate properly as intended.

Please refer to **Section 14. Substantial Equivalence Discussion** for detail information.

7. Discussion of Clinical Tests Performed:

The subject device HL858DM is compliant to the standard of ISO 81060-2:2018 Non-invasive sphygmomanometers- Part 2: Clinical validation of automated measurement type. 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 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 10993-1:2018, 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 Edition1.1 2013-07 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.1.0 (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 62366:2015 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's concluded that the subject device is substantially equivalent to the predicate device.