May 20, 2019

Health & Life Co., Ltd.
Js Hsu
Manager
9F, No. 186, Jian Yi Road
Zhonghe District, New Taipei City, 23553
TAIWAN

Re: K190134
Trade/Device Name: Full Automatic (NIBP) Blood Pressure Monitor, HL158TB
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 3, 2019
Received: April 22, 2019

Dear Js Hsu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Matthew Hillebrenner
Director (Acting)
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)*

K190134

Device Name

Full Automatic (NIBP) Blood Pressure Monitor, Model HL158TB

Indications for Use *(Describe)*

HL158TB 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.

HL158TB 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PREMARKET NOTIFICATION
510(K) SUMMARY
(As Requirement 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:
   Health & Life Co., Ltd.
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2. Name of the Device:
   Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL158TB
   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: HL158TA (K160336)

4. Device Description:
   HL158TB 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.13.5 cm to 19.5 cm) and for home use.

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.

5. Intended Use

HL158TB 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.

HL158TB 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

Table 6.1 Product Specification Comparison Table of Subject Device HL158TB, and Predicate Device HL158TA (K160336)

Item	Predicate Device HL158TA (K160336)	Subject Device HL158TB
Method of measurement	Oscillometric	Same as left
Measurement Type	During inflation	Same as left
Range of measurement	Rated Range of Cuff 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
Inflation	Automatic Inflation (Air Pump)	Same as left
Deflation	Automatic Air Release Control Valve	Same as left
Pressure Changed Rate	2~5mmHg/sec.	Same as left

Display	Liquid Crystal Digital	Same as left
Power Supply	2 ”AAA(LR03)(1.5V)”Alkaline Batteries	Same as left
Storage/Transportation environment	-25°C~70°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. 700~1060 hPa	Same as left
Material	ABS housing and ABS keys	Same as left
Sets of memory	1*60, total 60	Same as left
Number of push Button	2 keys (Start/Stop, M(Memory))	3keys (Start/Stop, M(Memory), Date/Time(◷))
Cuff size	Wrist circumference approx. 135 ~ 195 mm (Approx. 5.3~7.7 inches)	Same as left
Unit weight (excluding batteries)	Approx. 91.7 ± 10 g	Approx. 120 ± 10 g
Risk Category Indicator	AHA 2003	AHA 2017
Irregular Heartbeat Detector	Yes	Same as left
Error icon	EE & E1 & E2 & E3	& EE & E1 & E2 & E3

Changes from the predicate devices HL158TA (K160336):

* Changing the 2 keys to the 3 keys.
* Update the Risk Category Indicator.
* Modifying error icon.

These additional features have been verified and validated and do not affect the safety and effectiveness of subject device HL158TB.

7. Discussion of Clinical Tests Performed

The subject device HL158TB and the predicated device HL158TA (K160336) have the same method of measurement, measure type, critical components (ex. air pump, sensor…) and algorithm, so clinical study results can be transferred from the K160336 predicate to the subject device.

In ISO 81060-2 Second Edition 2013-05-01 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:
   - 19-8, IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests

b. Safety Test
   - 19-4, IEC 60601-1:2005+A1:2012/ AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
   - 19-14, IEC 60601-1-11 Edition 2.0 2015, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

c. FCC Test
   - FCC 47 CFR Part 15, Subpart B

d. Biocompatibility Test
   - 2-220, ISO 10993-1 Edition 4:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
   - 2-245, ISO 10993-5 Edition 3:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
   - 2-174, ISO 10993-10 Edition 3:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

e. Reliability Test
   - 3-123, IEC 80601-2-30 Edition 1.1:2013, Medical electrical equipment

- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

f. Risk Assessment
   - 5-40, ISO 14971 Edition 2:2007, Medical devices - Application of risk management to medical devices

g. Software Verification and Validation
   - 13-79, IEC 62304 Edition 1.1:2015, Medical device software - Software life cycle processes
   - IEC 60601-1-4 Edith1.1:2000 , Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems

h. Usability Validation ()
   - 5-114, IEC 62366-1 Edition 1.0:2015, Medical devices - Part 1: Application of usability engineering to medical devices
   - 5-89, IEC 60601-1-6 Edition 3.1:2013, 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.