August 2, 2019

Shenzhen Med-link Electronics Tech Co, Ltd.
Baihan Feng
Regulatory Affairs Specialist
4th Fl, Bldg A, Yingtailong Industrial Prk,
Dalang South Road, Longhua District
Shenzhen, 518109
CHINA

Re: K181154
Trade/Device Name: Med-link Wrist Digital Blood Pressure Monitor Model: ESM101,
Med-link Upper Arm Digital Blood Pressure Monitor Model: ESM201
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 28, 2019
Received: July 1, 2019

Dear Baihan Feng:

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 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)*
K181154

Device Name
Med-link Wrist Digital Blood Pressure Monitor Model:ESM101
Med-link Upper Arm Digital Blood Pressure Monitor Model:ESM201

Indications for Use *(Describe)*
Med-link Wrist Digital Blood Pressure Monitor is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the wrist. It can be used by medical professionals or at home. The cuff circumference is limited to 13.5-19.5 cm.

Med-link Upper Arm Digital Blood Pressure Monitor is non-invasive measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the upper arm. It can be used by medical professionals or at home. The cuff circumference is limited to 22-32cm.

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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Shenzhen Med-link Electronics Tech Co., Ltd.

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Type of submission: Traditional

The assigned 510(k) number is:_____

1. Submitter information

Manufacturer Name: Shenzhen Med-link Electronics Tech Co., Ltd.

Address: 4th Fl, Bldg A, Yingtailong Industrial Park, Dalang South Road, Longhua District, Shenzhen, Guangdong, CHINA, 518109

Tel: 0086-755-61568825

Fax: 0086-755-61120055

Establishment Registration Number: 3006636961

2. Contact Person

Baihan Feng (Primary Contact)

E-mail: MDL001@medlinket.com

Fei Liu

E-mail: USER22@med-linket.com

3. Data of Submission

28th , Jun., 2019

4. Identification of the Device

Trade Name: Med-link Wrist Digital Blood Pressure Monitor Model:ESM101

Med-link Upper Arm Digital Blood Pressure Monitor Model:ESM201

Common Name: Non-invasive blood pressure measurement system

Classification Regulation: 21 CFR 870.1130

Product Code: DXN

5. Identification of the Predicate Device

Table 1 Predicate Device Information

No.	Device Name	Common	Manufacture	Classifica	Classifi	510(k)

		Name		tion and Code	cation regulation	number
1	Full Automatic(NIBP) Blood Pressure Monitor, Model HL158LA	Blood Pressure Monitor	Health & Life Co.,Ltd.	Class II, DXN	21 CFR 870.1130	K130564
2	AGE Automatic Upper Arm Blood Pressure Monitor	Noninvasive blood pressure measurement system	Ageless Health Industrial Ltd.	Class II, DXN	21 CFR 870.1130	K123882

6. Indications for Use of the Subject device

Med-link Wrist Digital Blood Pressure Monitor is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the wrist. It can be used by medical professionals or at home. The cuff circumference is limited to 13.5-19.5 cm.

Med-link Upper Arm Digital Blood Pressure Monitor is non-invasive measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the upper arm. It can be used by medical professionals or at home. The cuff circumference is limited to 22-32cm.

7. Device Description

The proposed devices are battery driven automatic non-invasive blood pressure Monitor. It is used for automatically conduct the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult at wrist or upper arm within its claimed range and accuracy by oscillometry technique. Devices are consisted of three main parts: external hardwares (such as cuff), analog circuit, and MCU. The devices have the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time.
The proposed devices are intended to be used in medical facilities or at home and provided non-sterile.
The proposed devices have 2 models:
Med-link Wrist Digital Blood Pressure Monitor Model:ESM101

8. Test Summary

A series of safety, essential performance and biocompatibility tests were performed to assess the safety and effectiveness of Med-link Digital Blood Pressure Monitor. The tests listed below were conducted in accordance with

IEC 60601-1 Medical electrical equipment-Part 1:General requirements for basic safety, and essential performance.

IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 80601-2-30, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers

ISO 81060-2 Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type

ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Biological Evaluation of medical devices-Part 5: Test for in vitro cytotoxicity

ISO 10993-10 Biological evaluation of medical devices- Part 10: Tests For Irritation And Skin Sensitization

- Cytotoxicity Test
- Skin irritation Test
- Skin Sensitization Test

9. Substantial Equivalence Determination

Table 2 Comparison Table for Med-link Wrist Digital Blood Pressure Monitor ESM101

Item	Proposed Device	Primary Predicate Device
Trade name	Med-link Wrist Digital Blood Pressure Monitor	Full Automatic(NIBP) Blood Pressure Monitor, Model HL158LA
510(K) Submitter	Shenzhen Med-link Electronics Tech Co., Ltd.	Health & Life Co.,Ltd.
510(K) Number	—	K130564
Classification Regulation	21CRF 870.1130	21CRF 870.1130

Item	Proposed Device	Primary Predicate Device
Classification and Code	Class II, DXN	Class II, DXN
Common name	Noninvasive blood pressure measurement system	Blood Pressure Monitor
Type of Use	OTC	OTC
Indications for Use	Med-link Wrist Digital Blood Pressure Monitor is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the wrist. It can be used by medical professionals or at home. The cuff circumference is limited to 13.5-19.5 cm.	HL158LA 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 wrist. The intended use of this over-the-counter device is for use by people over the age of 18 with wrist circumference ranging from approx. 5.3 to 7.7 inches(13.5 cm to 19.5 cm) and for home use.
Patient populations	Adult	Adult
Method of Measurement	Oscillometric	Oscillometric
Measurement Site	Wrist	Wrist
Measurement Range	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute
Accuracy	Pressure: ±3mmHg Pulse: ±5%	Pressure: ±3mmHg Pulse: ±5%

Item	Proposed Device	Primary Predicate Device
Inflation and Deflation	Automatic	Automatic
Display	LCD	LCD
Memory	2x90 sets	4x30 sets
Cuff Size	13.5cm~19.5cm	13.5cm~19.5cm
Voice broadcast	Yes	Not-provided
Power Supply	DC 3.0V (2xAAA alkaline battery)	DC 3.0V (2xAAA alkaline battery)
Operation Environment	Temperature: +5° C~+40° C; Humidity: 15%~85%RH,	Temperature: +5° C~+40° C; Humidity: 15%~93%RH
Storage Environment	Temperature: -20° C~+55° C Humidity: ≤95%RH, non-condensing	Temperature: -25° C~+70° C Humidity: ≤95%RH,
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1, IEC 60601-1-11
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Performance	ISO 80601-2-30 and ISO 81060-2	AAMI SP10
Biocompatibility Evaluation	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993-1, -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993-1, -5, -10.

Table 3 Comparison Table for Med-link Upper Arm Digital Blood Pressure Monitor ESM201

Item	Proposed Device	Primary Predicate Device
Trade name	Med-link Upper Arm Digital Blood Pressure Monitor	AGE Automatic Upper Arm Blood Pressure Monitor
510(K) Submitter	Shenzhen Med-link Electronics Tech Co., Ltd.	Ageless Health Industrial Ltd.
510(K) Number	—	K123882
Classification Regulation	21CRF 870.1130	21CRF 870.1130

Item	Proposed Device	Primary Predicate Device
Classification and Code	Class II, DXN	Class II, DXN
Common name	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system
Type of Use	OTC	OTC
Indications for Use	Med-link Upper Arm Digital Blood Pressure Monitor is non-invasive measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the upper arm. It can be used by medical professionals or at home. The cuff circumference is limited to 22-32cm.	AGE Automatic Upper Arm Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 24-34cm.
Patient populations	Adult	Adult
Method of Measurement	Oscillometric	Oscillometric
Measurement Site	Upper Arm	Upper Arm
Measurement Range	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute
Accuracy	Pressure: ±3mmHg Pulse: ±5%	Pressure: ±3mmHg Pulse: ±5%
Inflation and Deflation	Automatic	Automatic

Item	Proposed Device	Primary Predicate Device
Display	LCD	LCD
Memory	2x90 sets	2x90 sets
Cuff Size	22cm~32cm	24cm~34cm
Voice broadcast	Yes	Yes
Power Supply	DC 6.0V (4xAA alkaline battery)	DC 6.0V (4xAA alkaline battery)
Operation Environment	Temperature: +5° C~+40° C; Humidity: 15%~85%RH,	Temperature: +5° C~+40° C; Humidity: 10%~95%RH
Storage Environment	Temperature: -20° C~+55° C Humidity: ≤95%RH	Temperature: -20° C~+65° C Humidity: 10%~95%RH
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Performance	ISO 80601-2-30 and ISO 81060-2	AAMI SP10
Biocompatibility Evaluation	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993-1, -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993-1, -5, -10.

The proposed device and its predicate devices have the identical indented use, principle and performance. The differences between the proposed device and the predicate device do not raise any question regarding its safety and effectiveness.

10. Conclusion

Based on the comparison and analysis in this submission, it can be concluded that: Med-link Upper Digital Blood Pressure Monitors are substantially equivalent to the predicate devices in regard to safety and effectiveness.