October 3, 2022

Zhuhai Linte Medical Instrument Co., Ltd.
℅ Becky Chen
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90,
Qianhai Road
Shenzhen, GuangDong 518052
China

Re: K220220
Trade/Device Name: Electronic Sphygmomanometer (Model: LT-P30)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 30, 2022
Received: August 30, 2022

Dear Becky Chen:

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,

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)*
K220220

Device Name
Electronic Sphygmomanometer (Models: LT-P30)

Indications for Use *(Describe)*
Measure blood pressure (systolic and diastolic) and pulse rate.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) Summary

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	Zhuhai Linte Medical Instrument Co., Ltd.
Address:	4th Floor, Building 1, No.66, Yongda Road, Hongqi Town, Jinwan District, Zhuhai, Guangdong, 519090 P.R.China
Contact person:	Wallace Huang
Phone number:	+86 13823146691
Email:	wallace.huang@lintemed.com
Date of summary prepared:	January 10, 2022
Reason for the submission:	New device, there were no prior submissions for the device.

(2) Proprietary name of the device

Trade name/model:	Electronic Sphygmomanometer /Model: LT-P30
Common name:	Blood Pressure Monitor
Classification name:	System, measurement, blood-pressure, non-invasive
Regulation number:	21CFR 870.1130
Product code:	DXN
Review panel:	Cardiovascular
Regulation class:	Class II

(3) Predicate device

Sponsor	A&D Engineering, Inc.
Device Name and Model	A&D Medical UA-651Digital Blood Pressure Monitor
510(k) Number	K141160
Product Code	DXN
Regulation Number	21CFR 870.1130
Regulation Class	Class II

(4) Description/ Design of device:

The Electronic Sphygmomanometer uses an inflatable cuff which is wrapped around the patient's upper arm. After the user pushes the "START/STOP" button, the cuff is inflated automatically by an internal pump. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by the internal

exhaust valve. There is a quick exhaust mechanism so that the cuff pressure can be completely released urgently. There is a maximum pressure safety setting at 300 mmHg. The device will not inflate the cuff higher than 300 mmHg. The device will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. At the end of the measurement, the systolic and diastolic pressures with pulse rate are shown on the LCD and stored in the device memory. The cuff is also deflated automatically to 0 mmHg at the same time.

(5) Intended use:

The Electronic Sphygmomanometer is intended for used by a person older than twelve (12) years to measure the systolic and diastolic blood pressure and pulse rate.

(6) Indications for use:

Measure blood pressure (systolic and diastolic) and pulse rate.

(7) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Arm cuff	210D raw silk cloth	Surface skin contact	Less than 24 hours

We have directly purchased arm cuff from qualified supplier which has obtained Biocompatibility test reports. For details, please refer to "Biocompatibility Discussion".

(8) Technological characteristics and substantial equivalence:

Item	Targeted device	Predicate device	Remark
Trade name	Electronic Sphygmomanometer (Models: LT-P30)	A&D Medical UA-651Digital Blood Pressure Monitor	/
510 (k) number	Pending	K141160	/
Regulation number	21CFR 870.1130	21 CFR 870.1130	Same
Regulation description	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Same
Product code	DXN	DXN	Same
Class	II	II	Same
Indications for use	Measure blood pressure (systolic and diastolic) and pulse rate.	Measure blood pressure (systolic and diastolic) and pulse rate.	Same
Intended use	The Electronic Sphygmomanometer is	The A&D Medical UA-651 family digital blood	Same

Item	Targeted device	Predicate device	Remark
	intended for used by a person older than twelve (12) years to measure the systolic and diastolic blood pressure and pulse rate.	pressure monitor is intended for used by a person older than twelve (12) years to measure the systolic and diastolic blood pressure and pulse rate.	
Intended patient	Person older than 12 years	Person older than 12 years	Same
Application sites	Upper arm	Upper arm	Same
Location for use	OTC	OTC	Same
Operation principle	Oscillometric	Oscillometric	Same
Measurement range	Pressure: 20-280mmHg Pulse Rate: 30-200bpm	Pressure: 20-280mmHg Pulse Rate: 30-200bpm	Same
Accuracy	Pressure: ±3mmHg or ±2% of measured value, whichever is greater; Pulse Rate: ±5%	Pressure: ±3mmHg or ±2% of measured value, whichever is greater; Pulse Rate: ±5%	Same
Display type	LCD	LCD	Same
Pressurization source	Automatic internal pump	Automatic internal pump	Same
Cuff deflation method	Standard exhaust valve	Standard exhaust valve	Same
Cuff attachment method	By plastic hose connected to monitor	By plastic hose connected to monitor	Same
Cuff design	D-ring cuffs	D-ring cuffs	Same
Cuff circumference	Small cuff: 17 ~ 22 cm Medium cuff: 22 ~ 32cm Large cuff: 22 ~ 42 cm	Small cuff: 16 ~ 24 cm Medium cuff: 23 ~ 37cm Large cuff: 31 ~ 45 cm	Similar - Within the scope of predicate device
Memory	45×3 recording of measurement data for multiple person	30 memories	Similar – does not affect the safety and effectiveness of the device
Power source	4 AA size batteries and	4 AA size batteries and AC	Similar

Item	Targeted device	Predicate device	Remark
	USB type-C cable as an option	adaptor as an option	
Operating Environment	Temperature: +5℃~+40℃; Humidity: 15～80%RH	Temperature: +10℃~+40℃; Humidity: 30～85%RH	Similar-does not affect the safety and effectiveness of the device
Storage Environment	Temperature: -40℃~+55℃; Humidity: ≤93%RH	Temperature: -20℃~+60℃; Humidity: 10～95%RH	Similar-does not affect the safety and effectiveness of the device
Compliance with voluntary standards	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO 10993-1,-5,-10 ISO 81060-2, IEC 80369-5	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO 10993-1,-5,-10 ISO 81060-2	Same

Conclusion:
Electronic Sphygmomanometer (Models: LT-P30) is substantial equivalent to the predicate device.

(10) Performance Data:
The performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below:

Non-Clinical Data
The following performance data have been conducted to verify that the Electronic Sphygmomanometer (Models: LT-P30) meets all design specifications which supports the conclusion that it’s Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the targeted device complies with the following standards:

Biocompatibility Testing:
The biocompatibility evaluation for the body-contacting component (arm cuff) of this

device was conducted in accordance with the "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Device - Part 1: Evaluation and Testing Within a Risk Management Process", as recongnized by FDA. The arm cuff has performed and passed the Biocompatibility test. So we have reason to believe that the arm cuff is safe for the users. The arm cuff complies with the following standards:

- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Electrical and EMC Safety:

The electrical safety and EMC safety testing was performed to, and passed, the following standards:

- ANSI AAMI ES60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11, 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
- 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

Performance:

The performance testing was performed to, and passed, the following standards:

- IEC 80601-2-30, Medical Electrical Equipment -- Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers
- IEC 80369-5, Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications

Software:

We have also conducted Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices".

Clinical Data

The clinical testing has been conducted per ISO 81060-2: 2018 Non-Invasive Sphygmomanometers -- Part 2: Clinical Validation of Automated Measurement Type on the Electronic Sphygmomanometer.

There are 120 subjected involved in the study, of which 61 female and 59 male. All the subjects are aged from 13 to 85. And the size distribution meets the requirements described in clause 5.1.4 of the standard.

The subject devices use the oscillometric method to measure blood pressure, the accuracy of determination depends on the sensor, race and ethnicity differences do not have an effect on the measuring result in the specified measuring scope.

During the testing, there were no adverse effects and complications occurred, and the results both meet criterion 1 and criterion 2 of ISO 81060-2.

Summary:

Based on the above non-clinical data and clinical data as documented in this application, the Electronic Sphygmomanometer was found to have a safety and effectiveness profile that is similar to the predicate device.

(11) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Electronic Sphygmomanometer is to be concluded substantial equivalent to its predicate devices.