October 24, 2024

Shenzhen Urion Technology Co.,Ltd.
℅ Wang Reanny
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.,Lt
Room 1407, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518107
China

Re: K241007
Trade/Device Name: Upper Arm Electronic Blood Pressure Monitor (U86E and TelliBP01)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 30, 2024
Received: September 30, 2024

Dear Wang Reanny:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241007

Device Name

Upper Arm Electronic Blood Pressure Monitor (U86E and TelliBP01)

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.

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Traditional 510(k) Summary

510(k) number: K241007

1. Information of Submitter and Correspondent

Submitter's information:

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Date Prepared: Aug. 05, 2024

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

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Contact Person: Reanny Wang

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2. Device Information

Trade Name: Upper Arm Electronic Blood Pressure Monitor

Model: U86E and TelliBP01

Common Name: Electronic Upper Arm Electronic Blood Pressure Monitor

Classification Name: System, measurement, blood-pressure, non-invasive;

Regulation: 21 CFR 870.1130

Device Class: Class 2

Product Code: DXN

3. Identification of Predicate Device(s)

Manufacturer	Zhuhai Linte Medical Instrument Co., Ltd.	Shenzhen AOJ Medical Technology Co., Ltd.
Legally Marketed Device	Electronic Sphygmomanometer	Arm Blood Pressure Monitor
510(K) Number	K220220	K222125

4. Description of Device

Upper Arm Electronic Blood Pressure Monitor, Model U86E and TelliBP01 are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the “oscillometric method”.

The main components of the Upper Arm Electronic Blood Pressure Monitor are the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately 22 cm to 42 cm, includes the inflatable bladder and fabric. The device consists of the main unit and cuff.

The product is provided non-sterile, and not to be sterilized by the user prior to use.

Model U86E and TelliBP01 in this submission follow the similar software, same measurement principle and similar specifications. The differences existed between different models included in this submission will not affect the safety and effectiveness of the device.

The model U86E embed an Bluetooth Wireless network connections module that allows it to send data(systolic blood pressure, diastolic blood pressure, pulse rate) from blood pressure monitor to the Application in the external instruments. The TelliBP01 embed a SIM card, which

can send data(systolic blood pressure, diastolic blood pressure, pulse rate) from blood pressure monitor to the Application in the external instruments through 4G network. The wireless functions of U86E and TelliBP01 only have data transmission function, without any control feature.

5. Intended use

Upper Arm Electronic Blood 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.

6. Indications for Use

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

7. Discussion of Non-Clinical Tests and clinical test Performed for Determination of Substantial Equivalence are as follows:

7.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Product service life
- Software validation
- Electromagnetic compatibility and electrical safety
- Bench Testing
- Biocompatibility test

All the test results demonstrate Upper Arm Electronic Blood Pressure Monitor meets the requirements of its pre-defined acceptance criteria and intended use, and it is substantially equivalent to the predicate device.

7.2 Clinical Testing

The clinical testing has been conducted per ISO 81060-2:2018/A1:2020 Non-Invasiv Sphygmomanometers -- Part 2: Clinical Validation of Automated Measurement Type on the Electronic Sphygmomanometer.

The clinical accuracy testing was performed on the U80EH Upper Arm Electronic Blood Pressure Monitor, which is also manufactured by the sponsor. The key factors affecting clinical trials, such as the intended use, measurement site, cuff size, working principle, and the core algorithms, are the same in U80EH, U86E and TelliBP01. Therefore, the clinical clinical accuracy testing for the model for U80EH is applicable for U86E and TelliBP01.

The study population consisted of 93 qualified participants with an average age of 54.81 years, 39 males and 54 females. A Mercury Sphygmomanometer was used as a reference device.

According to Criterion 1, the mean difference of systolic blood pressure measured by device-under-test and the reference device was 0.17mmHg, with a standard deviation of 7.52mmHg; the mean difference of diastolic blood pressure was 0.29mmHg, with a standard deviation of 5.35mmHg. The mean differences of both systolic blood pressure and diastolic blood pressure were less than 5mmHg, and the standard deviations were less than 8mmHg.

According to Criterion 2, the mean difference of systolic blood pressure measured by device-under-test and the reference device was 0.33mmHg, with a standard deviation of 6.84mmHg; The mean difference of diastolic blood pressure was 0.37mmHg, with a standard deviation of 4.77mmHg.

All the subjects completed the clinical study without adverse event.

The device-under-test fulfilled both validation criteria 1 and 2 of ISO 81060-2:2018/A1:2020.

8. Performance Summary

The devices conform to applicable standards as follow table:

Test Type	Standard Designation Number	FDA Recognition Status	Outcome for Device
Safety	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Yes	Conforms
EMC	IEC 60601-1-2:2020 IEC TS 60601-4-2: 2016	Yes	Conforms
Software	ANSI AAMI IEC 62304:2006/A1:2016	Yes	Conforms
Home healthcare environment	IEC 60601-1-11:2020	Yes	Conforms
Biocompatibility	ISO 10993-1:2018; ISO 10993-5:2009; ISO 10993-10:2010.	Yes	Conforms
Safety of Lithium battery	IEC 62133-2:2017	Yes	Conforms
Bench test	IEC 80601-2-30:2018	Yes	Conforms
Clinical test	ISO 81060-2:2018/A1:2020	Yes	Conforms

9. Discussion of Comparison to Predicate Devices.

The Upper Arm Electronic Blood Pressure Monitor submitted in this 510(k) submission is substantially equivalent in intended use, technological characteristics/ principles of operation and performance to the cleared Electronic Sphygmomanometer **K220220**, and Arm Blood Pressure Monitor **K222125**. Differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

Elements of Comparison	Subject Device	Primary Predicate Device (K220220)	Secondary Predicate Device (K222125)	Judgment
Trade name	Upper Arm Electronic Blood Pressure Monitor	Electronic Sphygmomanometer	Arm Blood Pressure Monitor	--
Model	TelliBP01, U86E	LT-P30	AOJ-30A, AOJ-30B, AOJ-30C, AOJ-30D, AOJ-30E, AOJ-30F and AOJ-30G	--
Company	Shenzhen Urion Technology Co.,Ltd.	Zhuhai Linte Medical Instrument Co., Ltd.	Shenzhen AOJ Medical Technology Co., Ltd.	--
Product code	DXN	DXN	DXN	Same
Classification	Class II	Class II	Class II	Same
Regulation #	21CFR870.1130	21CFR870.1130	21CFR870.1130	Same
Type of Use	OTC	OTC	OTC	Same
Application scenario	Medical Facilities and Home Use	Not publicly available	Medical Facilities and Home Use	Same
Indications for use	Measure blood pressure (systolic and diastolic) and pulse rate.	Measure blood pressure (systolic and diastolic) and pulse rate.	The Arm Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure, as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the upper arm at medical facilities or at home.	The same as the primary Predicate Device
Intended use	Upper Arm Electronic Blood 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.	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.		The same as the primary Predicate Device
Intended patient	Person older than 12 years	Person older than 12 years	adult	The same as the primary Predicate Device
Application sites	Upper arm	Upper arm	Upper arm	Same
Operation principle	Oscillometric	Oscillometric	Oscillometric	Same
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	Same
Blood pressure measurement range	SYS: 50mmHg~255mmHg DIA: 30mmHg~ 200mmHg	20-280mmHg	30-255 mmHg	Different, refer to Remark 1

Elements of Comparison	Subject Device	Primary Predicate Device (K220220)	Secondary Predicate Device (K222125)	Judgment
Pulse rate measurement range	40-199 beat/minute	30-200bpm	40-199 beat/minute	The same as the secondary predicate device
Accuracy	Pressure: ±3mmHg Pulse value: ±5% of reading	Pressure: ±3mmHg or ±2% of measured value, whichever is greater; Pulse Rate: ±5%	Pressure: ± 3 mmHg Pulse value: ± 5% of reading	Same
Display type	LCD	LCD	LCD	Same
Pressurization source	Automatic internal pump	Automatic internal pump	Not publicly available	The same as the primary Predicate Device
Cuff deflation method	Standard exhaust valve	Standard exhaust valve	Not publicly available	The same as the primary Predicate Device
Cuff attachment method	By plastic hose connected to monitor	By plastic hose connected to monitor	Not publicly available	The same as the primary Predicate Device
Cuff design	D-ring cuffs	D-ring cuffs	Not publicly available	The same as the primary Predicate Device
Cuff circumference	22 cm to 42 cm	Small cuff: 17 ~ 22 cm Medium cuff: 22 ~ 32cm Large cuff: 22 ~ 42 cm	22 ~ 42 cm	Same
Memory	90 measurements for each user (a total of 180 for two users)	45×3 recording of measurement data for multiple person	Not publicly available	Different, refer to Remark 2
Power source	TelliBP01: Rechargeable18650 lithium battery, 2000mAh. Charging input: DC 5V 1A. U86E: DC 6V, 4×AA batteries	4 AA size batteries and USB type-C cable as an option	6Vdc (4 *1.5V AAA batteries)	Different, refer to Remark 3
Operating Environment	Temperature range: +5℃ to +40℃, Relative humidity range: 15% to	Temperature: +5℃~+40℃; Humidity: 15～80%RH	Temperature: 5℃~ 40℃; Humidity: 15%–90% RH	Different, refer to Remark 4

Elements of Comparison	Subject Device	Primary Predicate Device (K220220)	Secondary Predicate Device (K222125)	Judgment
	93%			
Storage Environment	Temperature: -20℃ to +55℃, Relative humidity range: 10% to 93%	Temperature: -40℃~+55℃; Humidity: ≤93%RH	Ambient Temperature: -20℃ to 55℃ Relative Humidity: 10-93% RH	The same as the secondary predicate device
Compliance with voluntary standards	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30 IEC 60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11; IEC 80601-2-30; ISO 10993-1,-5,-10 ISO 81060-2	IEC 60601-1 IEC 60601-1-11 ISO 80601-2-30 IEC 60601-1-2 ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Patient Contacting	Surface-contacting, Less than 24 h	Not publicly available	Surface-contacting, Less than 24 h	Same
Biocompatibility evaluation	Cytotoxicity, skin sensitization and irritation	Cytotoxicity, skin sensitization	Cytotoxicity, skin sensitization	Same
WHO BP classification Indicator	Yes	Not publicly available	Yes	Same
Irregular heart beat prompt function	Yes	Not publicly available	Not publicly available	Different, refer to Remark 5
Speaking function and Clock reminder	U86E: no TelliBP01: yes	Not publicly available	Not publicly available	Different, refer to Remark 6
Weight	TelliBP01: Approx.273 g (without battery and cuff) U86E: Approx. 345g (without the battery and cuff)	Not publicly available	AOJ-30A/AOJ-30B/ AOJ-30G: (262±5) g without battery AOJ-30C: (316±5) g without battery AOJ-30D: (349±5) g without battery AOJ-30E: About 220 g without battery AOJ-30F: About 220 g without battery	Different, refer to Remark 7
Dimensions	TelliBP01: Approx.130 mm×95 mm×52.5mm U86E: Approx.L135mm x	Not publicly available	AOJ-30A/AOJ-30B/ AOJ-30G:127 mm * 93 mm * 73 mm AOJ-30C:108 mm * 139	Different, refer to Remark 7

Elements of Comparison	Subject Device	Primary Predicate Device (K220220)	Secondary Predicate Device (K222125)	Judgment
	W100mm x H53mm		mm * 62 mm AOJ-30D:136 mm * 113 mm * 68 mm AOJ-30E/AOJ-30F:118 mm * 98 mm * 61mm	
Data transmission	U86E: Has wireless function with Bluetooth TelliBP01: Has wireless function with 4G	Not publicly available	Has wireless function with Bluetooth and available for AOJ-30A and AOJ-30B only	U86E is the same as the secondary predicate device; TelliBP01 is Different, refer to Remark 8

Comparison discussion:

Remark 1: The Blood pressure measurement range of subject device is different from that of predicate devices, but the blood pressure measurement range of subject device is within the range of predicate devices. In additional, the subject device had passed the testing of IEC 80601-2-30 and ISO 81060-2 standards.So the difference will not raise any safety or effectiveness issue.

Remark 2: Although the memory groups between the predicate device and subject devices are different, they both comply with the IEC 80601-2-30 and ISO 81060-2 standards, so the difference will not raise safety or effectiveness issue.

Remark 3: Although the device power sources among the predicate devices and subject device are different, they are all complied with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 80601-2-30. So the minor difference do not affect the safety and effectiveness.

Remark 4: Although the Operating Environments of predicate devices and subject device are different, they are all complied with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and IEC 80601-2-30. So the minor differences do not affect the safety and effectiveness.

Remark 5: Irregular heart beat prompt does not influence the accuracy, and the Irregular heart beat prompt function have been verified by software test. so the difference will not raise safety or effectiveness issue.

Remark 6: Speaking function and Clock reminder do not influence the accuracy, and the Speaking function and Clock reminder function of TelliBP01 have been verified by software test. so the difference will not raise safety or effectiveness issue.

Remark 7: Although the “Dimension” and “Weight” between the predicate devices and subject device are different, they all comply with IEC 60601-1 and IEC 60601-1-2, so the differences do not affect the safety and effectiveness.

Remark 8: Although the data transmission between the TelliBP01 subject device and the secondary predicate device is different. the software validation and performance testing, as well as FCC testing, indicate that this difference will not cause any new performance and safety issues.

10. Conclusions

Verification and validation testing were conducted on the subject device and all testing passed pre-specified criteria. This premarket notification submission demonstrates that the Upper Arm Electronic Blood Pressure Monitor is substantially equivalent to the predicate devices.