K241129

ShenZhen GoodlyMed Technology Co., Ltd.
% Kyra Kang, Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza, West Guangzhong Road
Jingan District, Shanghai
China

Re: K241129
Trade/Device Name: Upper Arm Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 23, 2024
Received: April 24, 2024

Dear Kyra Kang:

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.

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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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241129

Device Name

Upper Arm Electronic Blood Pressure Monitor

Indications for Use *(Describe)*

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.

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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510(k) Summary

I. Submitter

ShenZhen GoodlyMed Technology Co.,Ltd.
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Submission Correspondent

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Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Upper Arm Electronic Blood Pressure Monitor
Common name:	Electronic Blood Pressure Monitor
Regulation Number:	21 CFR 870.1130
Regulatory Class:	Class II
Product code:	DXN
Review Panel:	Cardiovascular

III. Predicate Devices

510(k) Number:	K160019
Trade name:	U80 Series Electronic Blood Pressure Monitor
Common name:	Electronic Blood Pressure Monitor
Classification:	Class II
Product Code:	DXN
Manufacturer	Shenzhen Urion Technology Co., Ltd.

IV. Device description

The Upper Arm Electronic Blood Pressure Monitor uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsation , which is used to determine the systolic and diastolic pressure, and also pulse rate.

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.

There are two models of cuffs that can be used together：22-42cm and 32-52cm

This device has two series：A01(including A01-SLB, A01-BS, A01-BL, A01-SL, A01) and A02 (including A02-SE4、A02-SEB、A02-BE、A02-SE、A02-E)

They have same Indications for use and similar technological characteristics, the electrical circuit design, critical components used and internal wiring are also similar.We chose model A02-SE4 with the most complex functions as the representative model.

V. Indication for 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.

VI. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison of Upper Arm Electronic Blood Pressure Monitor

Characteristics	**Proposed device**	**Predicate device (K160019)**	**Discussion**
Product Code	DXN	DXN	Same
Indications For 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.	U80 Series Electronic 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. It can be used at medical facilities or at home. The intended	Same

		upper arm circumference is 22-36 cm.	
Measurement Type	Upper arm	Upper arm	Same
Patient Population	people over 12 years old	Adults Person over 12	Same
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	Same
Principle	Oscillometric	Oscillometric	Same
BP Range	0 ~ 299 mmHg	0 ~ 299 mmHg	Same
BP Accuracy	±3mmHg	±3 mmHg	Same
PR Range	40-199 bpm	40-199 bpm	Same
Cuff Size	Arm Circumference：22-42cm，32-52cm	Arm Circumference：22-36 cm	Similar
Power Supply	A01 Series：Four AAA batteries or AC adapter A02 Series：Four AA batteries or AC adapter	Four AA batteries or AC adapter	Similar
Software Level Concern	Moderate	Moderate	Same

Wireless	A01：bluetooth A02:4G	/	Different 1

Analysis 1

The subject device has Wireless module while the predicate device does not. However, it is to transfer measurement results only. As for the wireless technology of the subject device, it has also been validated according to Relevant standards. As demonstrated in relevant test reports, the difference here does not raise any issues concerning safety and effectiveness.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The biocompatibility testing includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Electrical Safety, EMC, Performance testing

- IEC 60601-1: 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 60601-1-6: Medical Electrical Equipment - Part 1-6: General requirements for safety – Collateral Standard: Usability.
- IEC 62366-1: Medical devices – Application of usability engineering to medical devices.

- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 80601-2-30: Medical electrical equipment – 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.

Wireless testing

- ANSI C63.27-2021 American National standard for evaluation of wireless coexistence
- AAMI TIR69:2017/(R2020) Risk management of radio-frequency wireless coexistence for medica devices and systems
- Radio frequency wireless technology in medical devices Guidance for industry and food and drug administration staff（August 14,2013）
- FCC Part 15 Subpart C 10-1-2022 Edition Part 15-Radio frequency devices Subpart C-Intentional Radiators

Cybersecurity

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Shelf-life

- 5-year shelf-life of the device has been evaluated by Shelf-life test.

Reprocessing

- ISO 17664 Processing of health care products —Information to be provided by the medical device manufacturer for the processing of medical devices

VIII. Clinical Testing

The device was tested according to ISO 81060-2:2018+A1:2020 Non-invasive sphygmomanometers – Part 2: Clinical validation of intermittent automated measurement type. Two clinical studies were performed on the device matching with different models of cuff. The study population consisted of 87, and 86 qualified subjects

respectively. all subjects were adults. All data’s mean error and standard deviation of differences in systolic, diastolic pressure is not beyond the limits set as per ISO 81060-2:2020. No adverse effect and/or complications are found in this study.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is as safe and effective as the predicate device. Accordingly, the proposed device is substantially equivalent to the predicate device.