January 26, 2021

Bioland Technology Ltd.
Yiqing Feng, RA
No. A6B7 (Block G), ShangRong Industrial Zone
No. 5 Baolong Road
Shenzhen, Guangdong 518116
China

Re: K202934
Trade/Device Name: Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 24, 2020
Received: December 28, 2020

Dear Yiqing 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,

for LT 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)*
K202934

Device Name

Blood Pressure Monitor, 2008, A221-2

Indications for Use *(Describe)*

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

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

A. Applicant

Name: Bioland Technology Ltd.

Adress: No. A6B7 (Block G)Shangrong Industrial. Zone, No.5 Baolong Road, Baolong Community Longgang District, 518116Shenzhen, Guangdong PEOPLE'S REPUBLIC OF CHINA

Tel: +86 755 3690 0999

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Contact person: Yiqing Feng

E-mail: regulator-a@bioland.com.cn

B. Subject device

Trade name: Blood Pressure Monitor
Model: 2008, A221-2
Classification name: System, Measurement, Blood-Pressure, Non-Invasive
Regulation Medical Specialty: Cardiovascular
Product Code: DXN
Regulation number: 830.1130
Device class: Class II
Code of Federal Regulations: 21CFR 870.1130

C. Predicate Device

Device name: Blood Pressure Monitor
K number: K201467
Manufacturer: Bioland Technology Ltd.

D. Indication for use

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

E. Device Description

The 2008, A221-2 blood pressure monitor contains shell, button, display screen, air tube, cuff and battery. The systolic, diastolic blood pressures and heart beats are transmitted via air pressure in the inflated cuff to transducer for the determination with oscillometric method. The cuff integrated with bladder is inflated by air pump. The deflation rate is controlled and released by a preset mechanical valve at a constant rate beginning at the pressure peak during the measurement. The measurement results including diastolic, systolic pressures and heart pulse rate are displayed on the LCD.

F. Substantial Equivalence table

Device	Subject Device	Predicate Device	Remarks
Manufacturer	Bioland Technology Ltd	Bioland Technology Ltd	N/A
Model	2008, A221-2	2005	N/A
Classification	II	II	Same
Product code	DXN	DXN	Same
Classification name	System, Measurement, Blood-Pressure, Non-Invasive	System, Measurement, Blood-Pressure, Non-Invasive	Same
Regulation No.	870.1130	870.1130	Same
510(K) number	N/A	K201467	N/A
Intended Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Same
Environmental of use	Home	Home	Same
Patient Population	Adult	Adult	Same
Measurement Site	Upper arm	Upper arm	Same
Measurement method	Oscillometric method	Oscillometric method	Same
Measurement range	Pressure: 0 to 300 mmHg Pulse Rate: 40 to 195 beats/min	Pressure: 0 to 300 mmHg Pulse Rate: 40 to 195 beats/min	Same
Pressure sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	Same
Measuring accuracy	Pressure: Within ±3mmHg Pulse Rate: Within ±5%	Pressure: Within ±3mmHg Pulse Rate: Within ±5%	Same
Cuff	22-32cm	22-32cm	Same
Inflation method	Automatic by electric pump	Automatic by electric pump	Same
Deflation method	Automatic pressure release valve	Automatic pressure release valve	Same
Power Source	4*AA batteries	4*AA batteries	Same
Display	LCD Display	LCD Display	Same
Operating Environment Condition	5~40^{o}C (41^{o}F ~104^{o}F), 15%~85% RH (non-condense)	15 ^{o}C~40^{o}C(59^{o}F ~104^{o}F), RH≤85% (non-condense)	Similar
Storage Environment Condition	-20~55^{o}C(-4^{o}F~131^{o}F), RH≤93% (non-condense)	-20~55^{o}C(-4^{o}F~131^{o}F), RH≤93% (non-condense)	Same

Device	Subject Device	Predicate Device	Remarks
Memory	2*50 sets (2008) 50 sets (A221-2)	128 sets	Different Note 1
Auto power off time	Within 3min	Within 3min	Same
Weight	Approx 208g (Not including battery)	Approx. 313g (Including battery)	Different Note 2
Dimension (L*D*H)	135mm*100mm*53mm	130mm*95mm*53mm	Different Note 3
Irregular Heart beat Feature	Yes	Yes	Same
Low battery indication	Yes	Yes	Same
Classify blood pressure level bar	Yes	No	Different Note 4
Patient contact materials	Surface contact Skin Limited duration of use<24 hours	Surface contact Skin Limited duration of use<24 hours	Same
EMC	IEC 60601-1-2:2014	IEC 60601-1-2:2014	Same
Electrical Safety	IEC 60601-1:2005/A1:2012	IEC 60601-1:2005/A1:2012	Same
Performance	IEC 80601-2-30	IEC 80601-2-30	Same
Biocompatibility	ISO 10993-5: 2009 ISO 10993-10: 2010	ISO 10993-5: 2009 ISO 10993-10: 2010	Same
Clinical	ISO 81060-2	ISO 81060-2	Same

Note 1: The memory size of subject device and predicate device are different. But the difference is very slight, it will not affect the main function and the intended use of the subject device. At the same time memory size of subject device is clearly indicated in user manual and gift-box. Therefore, the difference will not result in safety and effectiveness issue of the subject device.

Note 2 and Note 3: The weight and dimension between the subject device and predicate device is a little different, but the difference will not affect the main function and the intended use of the subject device, furthermore the weight and dimension is indicated in the user manual and gift-box. Thus, the difference will not result in safety and effectiveness issue of the subject device.

Note 4: The subject device has the “Classify blood pressure level bar” function and the predicate device is not. The “Classify blood pressure level bar” function will not affect the main function and the intended use of the subject device, meanwhile the “Classify blood pressure level bar” function of subject device is clearly indicated in user manual. So the difference will not result in safety and

effectiveness issue of the subject device.

G. Predicate Device Comparison

The subject device and the predicate device have the same intended use, same measuring range, measuring accuracy and the other similar technical parameters, they both use cuff oscillometric method to detect blood pressure and pulse rate. Thus, the subject device is substantially equivalent to the predicate device.

H. Non-clinical test

Testing name	Referenced standard	Summary result	Verdict
Electric safety testing	IEC 60601-1: 2005/A1;:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance FDA Recognition number: 19-4	The subject complies with the applicable requirements set forth in the referenced electric safety standard.	Pass
EMC testing	IEC 60601-1-2:2014Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests FDA Recognition number: 19-8	The subject complies with the applicable requirements set forth in the referenced EMC	Pass
Electric safety for medical device used in the home healthcare environment	IEC 60601-1-11:2015Medical electrical equipment – General requirements for basic safety and essential performance - Part 1-11: Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. FDA Recognition number: 19-14	The subject complies with the applicable requirements set forth in the referenced IEC 60601-1-11:2015	Pass
Performance testing	IEC 80601-2-30:2018 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers FDA Recognition number: 3-123	The subject complies with the applicable requirements set forth in the referenced performance standard.	Pass
Biocompatibility testing	ISO 10993-1:2018Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	The subject complies with the applicable requirements set forth in the referenced	Pass

Testing name	Referenced standard	Summary result	Verdict
	FDA Recognition number: 2-258 ISO 10993-5:2009Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity FDA Recognition number: 2-245 ISO 10993-10:2010Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity FDA Recognition number: 2-174	biological evaluation standard.	

I. Clinical Testing

Due to the subject device and predicate device (K number: K201467) having the same software algorithm, key components and cuff, the clinical report of blood pressure monitor (model: 2005,K number: K201467) can be applied to the traditional 510(k) as the clinical report of the subject device. Thus, the clinical data of the subject device came from the predicate device, and the clinical test information of the predicate device is as follows:

Name of clinical testing	Referenced standard	Summary of testing	Patient population (number of subjects)	Verdict
Clinical accuracy and repeatability testing	ISO 81060-2:2018 Non-Invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type. FDA Recognition number: 3-160	The methods and criteria of clinical accuracy and repeatability testing had been clinically assessed to meet the requirements of clinical accuracy per the referenced standards.	86 subjects	Pass

J. Conclusion

Non-clinical performance was conducted on the subject device and all tests met specified criteria. Based on the information provided in this submission, the subject device, 2008, A221-2 blood pressure monitor is substantially equivalent to the predicate device, Blood Pressure Monitor 2005.