September 21, 2020

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

Re: K201467
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: August 18, 2020
Received: August 25, 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,

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)*
K201467

Device Name
Blood Pressure Monitor, 2005, 2006, 2006-2, 2006-2B

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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, 518116 Shenzhen, 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: 2005, 2006, 2006-2, 2006-2B
Classification name: System, Measurement, Blood-Pressure, Non-Invasive
Regulation Medical Specialty: Cardiovascular
Product Code: DXN
Regulation number: 830.1130
Device class: Class 2
Code of Federal Regulations: 21CFR 870.1130

C. Predicate Device

Device name: HEM-9210T
K number: K163235
Manufacturer: Omron Healthcare, Inc.

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 2006-2B, 2006-2, 2006, 2005 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. The proposed device equipped with Bluetooth transmission function, which enable user to transmit the measurement results from the device to a mobile phone through Bluetooth. Users can manage the measurement results by the mobile application.

F. Substantial Equivalence table

Device	Subject Device	Predicate Device	Remarks
Manufacturer	Bioland Technology Ltd	Omron Healthcare, Inc	N/A
Model	2005, 2006, 2006-2, 2006-2B	HEM-9210T	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	K163235	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 method	Cuff oscillometric method	Cuff oscillometric method	Same
Measurement range	Pressure: 0 to 300 mmHg Pulse Rate: 40 to 195 beats/min	Pressure: 0 to 299 mmHg Pulse Rate: 40 to 180 beats/min	Similar
Pressure sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	Same
Measuring accuracy	Pressure: Within ±3mmHg Pulse Rate: Within ±5%	Pressure: Within ±3mmHg or 2% of reading Pulse Rate: Within ±5% of reading	Similar
Cuff	22-32cm	22-42cm	similar
Inflation method	Automatic by electric pump	Automatic by electric pump	Same
Deflation method	Automatic pressure release valve	Automatic pressure release valve	Same
Display	LCD digital display	LCD digital display	Same
Power Source	4*AA batteries	4*AA batteries or AC adapter	Similar
Display	LCD Display	LCD Display	Same
Operating Environment Condition	15~40^{o}C, RH≤85% (non-condense)	10 ^{o}C~40 ^{o}C, 15 to 90% RH	Similar
Storage Environment	-20~55^{o}C, RH≤93% (non-condense)	-20~60^{o}C, 10 to 95% RH	Similar

Device	Subject Device	Predicate Device	Remarks
Condition			
Dimension mm(L*D*H)	130*95*53 (2005) 140*109*60 (2006) 157*96*64(2006-2&2006-2B)	107*141*79	Different Note 1
Weight	Approx.313g (2005) Approx.350g (2006) Approx.495g (2006-2) Approx.496g (2006-2B) (Including battery)	Approx. 290g (10oz) (Not including battery)	Different Note 1
Irregular Heart beat Feature	Yes	Yes	Same
Bluetooth	Yes (only 2006-2B applied)	Yes	Similar
Low battery indication	Yes	Yes	Same
Patient contact materials	Surface contact Skin Limited duration of use<24 hours	Surface contact Skin Limited duration of use<24 hours	Same
Biocompatibility	ISO 10993-5: 2009 ISO 10993-10: 2010	ISO 10993-5: 2009 ISO 10993-10: 2010	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
Clinical	ISO 81060-2	ISO 81060-2	Same

Note 1: Although the appearance and weight of subject device and predicate device exits the difference, the difference is not a factor in function of the device; therefore, the difference of the appearance and weight has no influence on safety and effectiveness of product.

G. Predicate Device Comparison

The subject device and the predicate device have the same intended use and the similar technical parameters, they both use cuff oscillometric method to detect human body blood pressure and pulse rate. They have similar measuring range and measuring accuracy, only the appearance size and weight are different. Thus, the subject device is substantially equivalent to the predicate devices.

H. Non-clinical test

Testing name	Referenced standard	Summary result	Verdict
Electric safety	IEC 60601-1: 2005/A1: 2012 Medical electrical	The subject complies with the	Pass

testing	equipment Part 1: General requirements for basic safety and essential performance FDA Recognition number: 19-4	applicable requirements set forth in the referenced electric safety standard.	
EMC testing	IEC 60601-1-2:2014 Medical 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 60601-1-11:2015 Medical 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.	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 2-56: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers standards for performance effectiveness. FDA Recognition number: 3-123	The subject complies with the applicable requirements set forth in the referenced performance standard.	Pass
Biocompatibility testing	ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process FDA Recognition number: 2-258 ISO 10993-5: 2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity FDA Recognition number: 2-245 ISO 10993-10: 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity FDA Recognition number: 2-174	The subject complies with the applicable requirements set forth in the referenced biological evaluation standard.	Pass
QoS testing	47 CFR PART 15 Subpart C, Radio frequency devices subpart C – Intentional radiators	The subject complies with the applicable requirements set forth in the referenced	Pass

		standard.	

I. Clinical Testing

Name of clinical testing	Referenced standard	Summary of testing	Patient population (number of subjects)	Verdict
Clinical accuracy and repeatability testing	ISO 81060-2 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 and clinical tests were conducted on the subject device and all tests met specified criteria. Base on the information provided in this submission the subject device, 2005, 2006, 2006-2 and 2006-2B blood pressure monitor are substantially equivalent to the predicate device, Noninvasive Blood Pressure Measurement System, HEM-9210T.