October 7, 2022

InBody Co, Ltd.
℅ Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K221764
Trade/Device Name: BPBIO480KV
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 25, 2022
Received: August 29, 2022

Dear Daniel Kamm:

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)*
K22####

K221764

Device Name
BPBIO480KV

Indications for Use *(Describe)*

This blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 22 cm - 42 cm.

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 K221764

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Date prepared: August 24, 2022
Contact: Kichul Cha, CEO

1. Identification of the Devices:
   Proprietary-Trade Name: BPBIO480KV.
   Common/Usual Name: Blood pressure monitor
   Regulation Number: 21 CFR 870.1130
   Regulation Name: Non-Invasive Blood Pressure Meter
   Regulatory Class: Class II
   Product Code: DXN

2. Equivalent legally marketed device: K200442
   Proprietary-Trade Names: BP170; BP170B; BP160; BP160B; BPBIO250
   Common/Usual Name: Blood pressure monitor
   Regulation Number: 21 CFR 870.1130
   Regulation Name: Non-Invasive Blood Pressure Meter
   Regulatory Class: Class II
   Product Code: DXN

3. Indications for Use: This blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 22 cm – 42 cm.

4. Device Description: The BPBIO480KV is a digital monitor intended for use in measuring blood pressure and pulse rate in user population with upper arm circumference ranging from 22cm to 42cm (8.6-inch to 16.5-inch). The systolic blood pressure and diastolic blood pressure are measured by non-invasive blood pressure ("NIBP") measuring method and also by utilizing the Auto auscultation method and Oscillometric method. The BPBIO480KV may provide useful clinical information about the current health status of not only the users who are diagnosed with hypertension but also those who are not diagnosed with hypertension. Warnings and cautions described in the user's manual should be observed at all times. Automated Auscultation is a method that combines the accuracy of auscultation, and the convenience of the Oscillometric method. To measure the blood pressure, wrap the cuff around the upper arm and inflate it to a pressure above the systolic pressure. Then slowly release the air to detect the Korotkoff sound signal and the pressure sensor signal, which you can listen with the stethoscope attached to the cuff, to measure the systolic and diastolic blood pressure. The Automated Auscultation applied to BPBIO480KV combines the accuracy of the auscultation method with the convenience of easy measurement. The signals are electronically processed to compensate for the possible errors in the auscultation method caused by movement, external noise, etc., enabling a more accurate blood pressure measurement. Included components are the main unit, a large and a medium size cuff, a users manual, an AC adapter, a power cord, and an internal rechargeable lithium rechargeable battery. Measurement methods: Auscultation and Oscillometric.
   What is the Oscillometric method? The Oscillometric method is similar to the auscultation method,

where the cuff is inflated to reach above the systolic pressure and then deflated. The blood pressure is measured using the pressure change in the blood flow while the cuff is being deflated. Systolic, diastolic, and mean pressure are estimated based on Oscillometric waveforms generated by the pressure changes. Compared to auscultation, it is convenient because it is easy to use and is less affected by external noise or movement, so it is widely used in automatic blood pressure monitors. However, conventional automatic blood pressure monitors, which use their own estimation algorithms, have problems with different measurements and poor accuracy. To perform a measurement, BPBIO480KV inflates the cuff above the systolic pressure and then deflates it to obtain the cuff pressure value and Korotkoff sound. As the pressure falls to the patient's systolic blood pressure, the first Korotkoff sound is heard. When the pressure drops below the diastolic pressure, it disappears after the last Korotkoff sound is heard. BPBIO480KV determines whether a Korotkoff sound is heard using the volume, distribution, Oscillometric signal, and filter of the sound acquired during the measurement, and determines the blood pressure value.

What is Auscultation? Auscultation is a method of measuring blood pressure directly using stethoscope, pressure gauge, and a cuff. It is the most traditional and a recognized standard. Wrap the upper arm with a cuff, inflate the cuff to pressurize the artery that passes under the skin to completely occlude the blood flow. Then release the air to reduce pressure, and use a stethoscope to listen to the sound from the pressed arteries when blood flows back into the pressed area. The sound generated at this moment is called the Korotkoff sound, and it is known to be caused by turbulence caused by the blood flow. As the pressure in the cuff falls to or below the patient's systolic blood pressure, some blood will be able to pass through the upper arm and the first Korotkoff sound is heard. Korotkoff sound continues to be heard as long as the pressure in the cuff is between the systolic and diastolic pressures, and it disappears altogether when the pressure in the cuff drops below the diastolic pressure. When the pressure in the cuff drops below the diastolic pressure, the cuff no longer interferes with blood flow, so there is no more audible sound as the blood flows without the turbulence.

This equipment tracks and analyzes the blood flow oscillations under the pressure using the cuff from the highest to the lowest pressure when the minute pressure speed is determined by the heartbeat. This equipment adopts Oscillometric method **and** automated auscultation method using a cuff for blood pressure measurement. In case of Oscillometric method, the device determines the systolic, diastolic and average pressure on the basis of the blood flow oscillations measured through the cuff. The point where the maximum amplitude of the blood flow oscillation appeared is the average pressure, the points where the 70% and 60% amplitudes appeared are the systolic and the diastolic pressure respectively. On the other hand, in case of Auto auscultation method, it is a method that combines the accuracy of auscultation, which is regarded as the gold standard for blood pressure measurement. To measure the blood pressure, wrap the cuff around the upper arm and inflate it to a pressure above the systolic pressure. Then slowly release the air to detect the Korotkoff sound signal and the pressure sensor signal, which you can catch with the stethoscope attached to the cuff, to measure the systolic and diastolic blood pressure. The Automated Auscultation applied to BPBIO480KV combines the accuracy of the auscultation method that the medical staffs hear directly with the convenience of easy measurement. The signals are electronically processed to compensate for the possible errors in the auscultation method caused by movement, external noise, etc., enabling a more accurate blood pressure measurement.

5. Safety and Effectiveness, comparison to predicate device. The testing results and specification comparisons indicate that the new models are as safe and effective as the predicate device. A comparison table is presented below.

Comparison table

Item	Predicate Device K200442 Proprietary-Trade Names: BP170; BP170B; BP160; BP160B; BPBIO250	Proposed Model BPBIO480KV	Comparison Result
Intended Use	The InBody blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 17cm - 42cm.	This blood pressure monitor is designed to measure blood pressure (diastolic and systolic) and pulse rate in adult patients with arm circumference range between 22 cm – 42 cm.	SAME (slightly different range of arm circumference.)
Patient Population	Adult	Adult	Same
Measurement location	Upper Arm	Upper Arm	Same
Measurement Principle	Oscillometric	Auto auscultation method and Oscillometric method	Similar
Measured:	Blood Pressure and Pulse	SAME	Same
Blood Pressure Cuff	External to the device	External to the device	same
Components	LCD, Cuff, MCU, Pump	LCD, Cuff, MCU, Pump	Same
Memory	Internal only, 99 readings	Internal or transfer to external USB stick. USB facilitates program update as well.	Similar
Power Source	BP170; 4-AA Size Alkaline (or AC Line) BPBIO250; Rechargeable Lithium with AC Line adapter	Rechargeable Lithium with AC Line adapter	Similar, rechargeable instead of AA.
Dimensions	BPBIO250: 122(W) x 150(L) x 195(H): mm	200(W) x 180(H) x 210(L) mm	Similar
Measurement range	Blood pressure: 40-300mmHg, Pulse rate: 30-240bpm	Blood Pressure 0-300mmHg, Pulse: 30-240bpm	Ranges are comparable.
Accuracy	BPBIO250: Pressure: Within ±3 mmHg, Pulse: Within ±3%	Pressure: ±3mmHg, Pulse: Within ±3%	SAME
Range of arm circumference	17cm - 42cm.	22cm-42cm	Similar
Memory	99 measurements	1000 measurements	More internal storage
External communication	NONE	USB for external measurement storage and program updates	More useful in the clinical environment

Item	Predicate Device K200442 Proprietary-Trade Names: BP170; BP170B; BP160; BP160B; BPBIO250	Proposed Model BPBIO480KV	Comparison Result
Photos	**BPBIO250** 	**BPBIO480KV** 	Similar appearance

6. Summary of technological characteristics of the device compared to the predicate device. This blood pressure/pulse rate meter is intended to be used in measuring human systolic, diastolic and pulse rate by oscillometric (or manual) method. Performance characteristics are in accordance with standards listed below. The substantial equivalence between these new meters and the predicate BPBIO250 can be evaluated from several aspects as listed in above table. The following FDA guidance was consulted in the design and testing of the device: *Non-Invasive Blood Pressure (NIBP) Monitor Guidance MARCH 1997, Final.*

7. Non-clinical testing: The proposed new model was tested and found to conform to the following international standards:

FDA Recognition #	Standard Number and Title.
19-4	IEC 60601-1:2005/A1:2012 ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-8	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
5-89	60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
3-123	ANSI AAMI IEC 80601-2-30:2018 Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated type non-invasive sphygmomanometers
3-166	ISO 81060-2 Third edition 2018-11 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type [Including: Amendment 1 (2020)]
2-282	ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice
2-258	ANSI AAMI ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2-245	ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2-174	ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
2-276	ISO 10993-18 Second edition 2020-01 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process.
5-117	ISO 15223-1 Third Edition 2016-11-01 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements

Because the unit has a USB port (for external storage of measurements and program updates) cybersecurity is a concern. We added cybersecurity precautions to the labeling and to our internal software generation and distribution procedures, after consulting the FDA guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff.* Our company is certified to ISO27001 Information technology — Security techniques — Information security management systems — Requirements.

8. Clinical Testing: Successful testing was performed according to (i) the ISO Standard 81060-2:2018 for clinical investigation of intermittent automated measurement type [1], (ii) the European Society of Hypertension recommendations for its clinical application, and (iii) the ISO 14155:2020 principles for Good Clinical Practice (Clinical investigation of medical devices for human subjects. There were 85 total subjects. Both cuff sizes were employed among 93 participants, both male and female, over the age of 12. A "Y" tube was used to connect both the automated meter and the standard mercury sphygmomanometer to the cuff. Validation Results: The system passed the deviation limits initially set by the protocol.

Conclusion, Comparison to the predicate device. Proposed Model BPBIO480KV is substantially equivalent to the predicate. The devices are identical in the intended use, and very similar in the design principles, the performance and the applicable standards. Only their appearance and the user interfaces are different.