August 2, 2023

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

Re: K231174
Trade/Device Name: BPBIO750
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 4, 2023
Received: July 5, 2023

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231174

Device Name
BPBIO750

Indications for Use *(Describe)*

The BPBIO750 is a digital monitor intended for use in measuring blood pressure and pulse rate in user population with left and right upper arm circumference ranging from 22 cm to 42 cm (8.7-inch to 16.5-inch). The systolic blood pressure and diastolic blood pressure are measured by non-invasive blood pressure ("NIBP") measuring method. The BPBIO750 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.

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 K231174

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Date prepared: July 3, 2023
Contact: Kichul Cha, CEO250

1. Identification of the Device:
   Proprietary-Trade Name: BPBIO750.
   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. Predicate Device (Substantial Equivalence): K131064
   Trade/Device Name: BPBIO320/BPBIO320n
   Regulation Number: 21 CFR 870.1130
   Regulation Name: Non-Invasive Blood Pressure Meter
   Regulatory Class: Class II
   Product Code: DXN

3. Indications for Use: The BPBIO750 is a digital monitor intended for use in measuring blood pressure and pulse rate in user population with upper arm circumference ranging from 22 cm to 42 cm (8.7-inch to 17-inch). The systolic blood pressure and diastolic blood pressure are measured by non-invasive blood pressure ("NIBP") measuring method. The BPBIO750 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.

4. Device Description: The InBody BPBIO750 is a kiosk-type, automated, single upper-arm cuff oscillometric BP monitor developed for self-measurement of BP in public spaces. It is designed for BP measurements on either the right or left upper arm and has a fixed tubular opening to insert the user's arm, with an integral single-arm cuff, which when inflated surrounds the upper arm. It is suitable for arm circumference range 22–42 cm. The device has an elbow groove to ensure correct positioning of the arm and measures BP during inflation. A wide LED screen presents systolic and diastolic BP, heart rate and time of measurement, and print-out of these data is provided automatically to the user. When the device is turned on, an auto zero calibration is performed, as well as a functional self-check of the air pressure change according to motor operation, the initial cuff position, and the motor load according to the cuff movement. Its weight is 7.1 kg, width 299 mm, depth 547 mm, height 485 mm, and has power supply through cable (AC 250 V, 10A). Calibration is recommended once every 12 months. Measurements are:
   - Pulse rate

- Systolic and diastolic blood pressure
- Mean Arterial Pressure [mmHg] [1/3 X SBP + 2/3 X DBP] (Caution: This is an ESTIMATED number). Source: https://en.wikipedia.org/wiki/Mean_arterial_pressure
- Pulse Pressure (P.P) is the difference between your systolic blood pressure and diastolic blood pressure. It changes with each stroke volume of the heart. In addition to changes in stroke volume, pulse pressure may increase depending on the degree of arteriosclerosis.
- Pressure Rate Product is the product of heart rate and systolic blood pressure

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 K131064 Trade/Device Name: BPBIO320/BPBIO320n**	**Proposed Model BPBIO750**	**Comparison Result**
Indications for 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.	The BPBIO750 is a digital monitor intended for use in measuring blood pressure and pulse rate in user population with upper arm circumference ranging from 22 cm to 42 cm (8.7-inch to 17-inch). The systolic blood pressure and diastolic blood pressure are measured by non-invasive blood pressure ("NIBP") measuring method. The BPBIO750 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.	Essentially the SAME, arm circumference range updated to validated size range.
Environment	Professional, not home	Professional, not home	Same
Patient Population	Adult	Adult	Same
Measurement location	Upper Arm	Upper Arm	Same
Measurement Principle	Oscillometric	Oscillometric	Same
Measured:	Blood Pressure and Pulse	Blood Pressure and Pulse PLUS Mean Arterial Pressure* Pulse Pressure (P.P)* Pressure Rate Product*	Greater functionality (computations)
Measurement Range	Blood Pressure: 40-300mmHg, Pulse Rate: 30-240bpm	Blood Pressure: 0-300mmHg, Pulse Rate: 30-240bpm	Functionally equivalent

Item	Predicate Device K131064 Trade/Device Name: BPBIO320/BPBIO320n	Proposed Model BPBIO750	Comparison Result
Accuracy	Pressure: ±3mmHg, Pulse Rate: ±2%	Pressure: ±2mmHg, Pulse Rate: ±1.5%	Not significantly different, improved accuracy
Blood pressure cuff	Internal to the device	Internal to the device	Same
Cuff material	Nylon +Polyurethane	Nylon +Polyurethane	Same
Range of Arm Circumference	17-42cm	22-42cm	Different
Components	LCD, Cuff, MCU, Pump	LCD, Cuff, MCU, Pump	Same
Power Source	AC Line	AC Line	Same
Energy saving	Not available	Automatically enters energy saving mode after 2 minutes of idle time	Does not affect functionality, saves energy when not actively being used
Dimensions	489(W) x 409(L) x 284(H) mm	299(W) x 547(L) x 485(H) mm	Different but functionally equivalent
External communication	RS-232	USB for external measurement storage and program updates	Updated
Printer	Yes	Yes	SAME
Photo			Different but functionally equivalent Slimmer.

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 BPBIO320/BPBIO320n 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. Objective The aim of this study was to evaluate the accuracy of the single upper-arm cuff oscillometric blood pressure (BP) monitor InBody BPBIO750 developed for self-measurement by adults in public spaces (kiosk) according to the Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Universal Standard (ISO 81060-2:2018).
   Methods: Subjects were recruited to fulfil the age, gender, BP and cuff distribution criteria of the AAMI/ESH/ISO Universal Standard in general population using the same arm sequential BP measurement method.
   A total of 102 subjects were recruited and 85 were analyzed [mean age 56.7 ± 15.4 (SD) years, 40 men, arm circumference 32.3 ± 5.3 cm, range 22–42 cm]. For validation criterion 1, the mean ± SD of the differences between the test device and reference BP readings was 2.2 ± 6.1/−2.2 ± 5.2 mmHg (systolic/diastolic). For criterion 2, the SD of the averaged BP differences between the test device and reference BP per subject was 5.00/4.63 mmHg (systolic/diastolic). Conclusion The InBody BPBIO750 device fulfilled all the requirements of the AAMI/ESH/ISO Universal Standard (ISO 81060-2:2018) in general population and can be recommended for clinical use in adults. Blood Press Monit 26: 146–148.

9. Conclusion, Comparison to the predicate device. Proposed Model BPBIO750 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.