January 6, 2021

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

Re: K200560
Trade/Device Name: InBody
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DXQ
Dated: December 5, 2020
Received: December 9, 2020

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,

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)*
K200560

Device Name
BPBIO210/220/210T/220T

Indications for Use *(Describe)*
The subject device is a manual blood pressure (BP) monitor, and requires the user to listen for Korotkoff sounds to determine systolic and diastolic pressure. Further, patients whose Korotkoff sounds are not clear or absent, such as children younger than 3 years of age, will not be suitable for the subject device. Pulse rate is also measured.

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 K200560

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TEL. +82 02-501-3939
Date prepared: January 5, 2021
Contact: Kichul Cha, CEO

1. Identification of the Devices:
   Proprietary-Trade Names:
   InBody Blood Pressure Monitor, BPBIO210/220/210T/220T.
   Regulation Number: 21 CFR 870.1130
   Regulation Name: Noninvasive blood pressure measurement system
   Regulatory Class: Class II
   Product Code: DXN, DXQ

2. Equivalent legally marketed device: K061456, A&D Engineering, Inc.
   Proprietary-Trade Names: A&D Medical UTM-101 Digital Blood Pressure Monitor
   Regulation Number: 21 CFR 870.1130
   Regulation Name: Noninvasive blood pressure measurement system
   Regulatory Class: Class II
   Product Code: DXN

3. Indications for Use: The subject device is a manual blood pressure (BP) monitor, and requires the user to listen for Korotkoff sounds to determine systolic and diastolic pressure. Further, patients whose Korotkoff sounds are not clear or absent, such as children younger than 3 years of age, will not be suitable for the subject device. Pulse rate is also measured.

4. Product Description: This device can be used to measure blood pressure and pulse rate non-persistently using the Korotkoff sound method of measuring blood pressure in vitro. The user can measure the blood pressure using this device and cuff, stethoscope. Basically, it has the same function as a conventional mercury sphygmomanometer. However, instead of using harmful mercury to the human body, it displays the pressure on the LCD screen, so that the blood pressure can be measured harmlessly to the human body. In addition, using the 'Mark' function can conveniently display the systolic and diastolic pressures. And using its backlight, the user can measure blood pressure in the dark place. If air pressure exceeds 320mmHg, it will automatically exhaust quickly. If an emergency occurs during the measurement, pressing On/Off button will turn off the equipment and allow rapid exhaust. The device is for use by medical professional. The testing person supplies their own stethoscope, which is required for making the measurements. The measurement method is as follows.
   1. BPBIO220/BPBIO210: Place the device on a sturdy table or the cart. For BPBIO220T/BPBIO210T: Assemble the stand and the device.
   2. Sit properly in chair and place patient's arm at heart height.
   3. Wind the cuff around the patient's arm.
   4. Pressurize manually.
   5. Depressurize manually and listen to the Korotkoff sound.

6. Determine the systolic blood pressure and the diastolic blood pressure by Korotkoff sound.
7. When the measurement is complete, the heart rate appears on the screen. The heart rate display is an incidental result of the Korotkoff sound identification and is not intended to be diagnostic or act as a heart rate monitor or alarm.

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.

Item	**K061456, A&D Engineering, Inc. UM-101 SPHYGMOMANOMETER**	**InBody Blood Pressure Monitor, BPBIO210/220/210T/220T.**	**Comparison Result**
Intended Use	Measure blood pressure (systolic and diastolic) and pulse rate.	The subject device is a manual blood pressure (BP) monitor, and requires the user to listen for Korotkoff sounds to determine systolic and diastolic pressure. Further, patients whose Korotkoff sounds are not clear or absent, such as children younger than 3 years of age, will not be suitable for the subject device. Pulse rate is also measured.	Same
Patient Population	Adult	Adult	Same
Measurement location	Upper Arm	Upper Arm	Same
Measurement Principle	Korotkoff sounds.	Korotkoff sounds.	Same
Measured:	Blood Pressure Pulse Rate	Blood Pressure and Pulse Rate	Same
Blood Pressure Cuff	External	External	Same
Inflation system	Manual	Manual	Same
Components	Gauge, Cuff, Pump	Gauge, Cuff, Pump	Same
Power Source	2 x 1.5V alkaline batteries (LR6 or AA)	4 x alkaline batteries (AA)	Similar, battery operation
Dimensions	12,7” Gauge, Rectangular	12.6” Gauge, Rectangular	Nearly identical.
Overpressure safety	An automatic quick exhaust valve is installed in the device to prevent over pressurization of 320mmHg or higher, therefore protecting the patient.	If air pressure exceeds 320mmHg, it will automatically exhaust quickly. If an emergency occurs during the measurement, pressing On/Off button will turn off the equipment and allow rapid exhaust	Same
Measurement range	Blood Pressure 0-300 mmHg, Pulse: 30-240 bpm	Blood Pressure 0-300 mmHg, Pulse: 30-240 bpm	Same
Measurement storage	Up to 5 measurements may be stored via a marking on the vertical LCD scale	Up to 5 measurements may be stored via a marking on the vertical LCD scale	Same.
Accuracy	Pressure: ±3mmHg Pulse: ±5 %	Pressure: ±3 mmHg, Pulse: ±3%	Essentially the same

Item	K061456, A&D Engineering, Inc. UM-101 SPHYGMOMANOMETER	InBody Blood Pressure Monitor, BPBIO210/220/210T/220T.	Comparison Result
Range of cuff sizes	Large cuff 33 cm to 45 cm Medium cuff 23 cm to 33 cm Small cuff 16 cm to 23 cm	Large cuff 32 cm to 42 cm Medium cuff 22 cm to 32 cm Small cuff 17 cm to 22 cm.	Similar range of sizes
Photos			Very similar in appearance.

6. Summary of technological characteristics of the device compared to the predicate device. These blood pressure meters are intended to be used in measuring human systolic, diastolic blood pressure using Korotkoff sounds. In addition to being able to manually measure (and store up to 5 measurements) this electronic version of the classical blood pressure meter can display pulse rate. 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 models were tested and found to conform to the following international standards:

   IEC 60601-1 :2005/AMD1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance FDA recognition 19-4

   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 19-8

   In additional to standards testing, we did bench testing to compare the proposed device results to the regular manual method of measuring blood pressure. InBody has implemented the bench testing procedure to determine the overall system accuracy of non-invasive sphygmomanometers with the intent to verity the overall accuracy of BPBIO210/220/210T/220T. 102 subjects were tested. The comparison results are as follows: InBody has compared the accuracy between mercury manometer using the stethoscope and the non-invasive sphygmomanometer, BPBIO210/220/210T/220T. We found and concluded that they are substantially equal to each other. The accuracy of the BPBIO210/220/210T/220T which acquired from the clinical investigation implemented by InBody is respectively the systolic (Mean = 0mmHg, Std. Dev = 1.206mmHg), and the diastolic (Mean = 0mmHg, Std. Dev = 1.424mmHg). This testing was done in accordance with EN 1060-4. Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers. This is an international version of SP-10 which is referenced in the FDA Guidance.

8. Clinical Testing: Not required for this type of device. Blood pressure measurement is manually done by the testing person.

9. Conclusion, Comparison to the predicate device. Proposed Models: BPBIO210/220/210T/220T. are substantially equivalent to the predicate whose 510(k) number is K061456. The devices are identical in the intended use, and similar in the design principles, the performance and the applicable standards. Only their appearance and the user interfaces are different.