December 4, 2020

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

Re: K200442
Trade/Device Name: InBody Blood Pressure Monitors: BP170; BP170B; BP160; BP160B; BPBIO250
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 3, 2020
Received: November 4, 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,

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)*
K200442

Device Name
InBody Blood Pressure Monitors: BP170; BP170B; BP160; BP160B; BPBIO250

Indications for Use *(Describe)*

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 models of BP170, BP170B, BP160 and BP160B are designated as both Prescription use and Over-the-counter use.

The model of BPBIO250 is designated as Prescription use only.

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 K200442

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Date prepared: December 2, 2020
Contact: Kichul Cha, CEO

1. Identification of the Devices:
   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

2. Equivalent legally marketed device: K131064, Biospace Corporation Limited (Former company name)
   Proprietary-Trade Names: BPBIO320/BPBIO320n
   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 (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.

4. Descriptions of the different models: All models have this common feature: Automatic blood pressure measurement using the oscillometric technique. This is the same method as our predicate. We have employed essentially the same technology as we used in our previous model (the predicate) but have packaged the unit differently in order to make it more portable. Instead of having a built in blood pressure cuff, we have moved that component outside of the unit so that now it plugs in to the measurement unit in the same way a large number of similar devices are designed. Instead of AC line operation only, the units can run on primary or on rechargeable batteries. The predicate device used an 8 bit microcontroller with 128Kbytes of in-system programmable flash memory. The BP170 series and the BPBIO250 use 32 bit microcontrollers with 128Kbytes of programmable flash. Most of the measurement software has been re-used from our predicate device and is virtually the same between the two new sets of models.

The BP170 is a fully automatic portable battery operated blood pressure monitor using the oscillometric technique which comes with batteries, a standard cuff, a storage pouch, and a user's manual. Model variations:

Model name	Options		
	One-touch Cuff	Normal Cuff	Bluetooth*
BP170	Yes	No	No
BP170B	Yes	No	Yes
BP160	No	Yes	No
BP160B	No	Yes	Yes

*Bluetooth is not currently supported. For future use. When implemented, it will operate as an MDDS, a medical device data system, product code OUG.

Photo of BP170

BPBIO250 This product is a professional automatic blood pressure monitor used by medical professionals. 5 measurement modes can be selected according to various medical environments. Rechargeable batteries can be used without replacing batteries. The User can measure blood pressure even in dark environments. - This blood pressure monitor has cuffs of various sizes. So, User can measure the blood pressure and measure pulse rate to children and adult patients whose arm circumferences are between 17 cm and 42 cm. Bluetooth, when implemented (future option) it will operate as an MDDS, a medical device data system, product code OUG.

Photo of BPBIO250

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	Predicate Device BPBIO320/BPBIO320n K131064, Biospace Corporation Limited (Our former company name)	Proposed Models: BP170; BP170B; BP160; BP160B; BPBIO250	Comparison Result
Intended Use	The Biospace 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 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.	SAME
Patient Population	Adult	Adult	Same
Measurement location	Upper Arm	Upper Arm	Same
Measurement Principle	Oscillometric	Oscillometric	Same
Measured:	Blood Pressure and Pulse Rage	SAME	Same
Blood Pressure Cuff	Internal to the device	External to the device	Makes the new device more portable
Components	LCD, Cuff, MCU, Pump	LCD, Cuff, MCU, Pump	Same
Power Source	AC Line	BP170; 4-AA Size Alkaline (or AC Line) BPBIO250; 4-AA Size Alkaline (or AC Line) Rechargeable Lithium with AC Line adapter	All of the new models can work on batteries.
Dimensions	489(W) x 409(L) x 284(H)mm	BP170; BP170B; BP160; BP160B: 99(W) X 191(L) X 26(H): mm BPBIO250: 122(W) x 150(L) x 195(H): mm	The new units are smaller
Measurement range	Blood pressure: 40-300mmHg, Pulse rate: 30-240bpm	BP170: 0-300 mmHg, Pulse: 30-240 bpm BPBIO250; 0-300mmHg, Pulse: 30-240 bpm	Ranges are comparable.
Accuracy	Pressure: ±3mmHg Pulse rate: ±2%	BP170: Pressure: ±3 mmHg, Pulse: Within ±3% BPBIO250: Pressure: Within ±3 mmHg, Pulse: Within ±3% : Pressure: ± 2mmHg Pulse: Within ± 1.5%	Accuracies are not significantly different. The new offers the best accuracy
Range of arm circumference	17cm - 42cm.	SAME 17cm-42cm	SANE

Item	Predicate Device BPBIO320/BPBIO320n K131064, Biospace Corporation Limited (Our former company name)	Proposed Models: BP170; BP170B; BP160; BP160B; BPBIO250	Comparison Result
Photos	BPBIO350 	New Models BP170, BPBIO250 	The new models take up less table space and use a traditional cuff.
Bluetooth	Not available	BP170B BP160B BPBIO250	Future option as MDDS

6. Summary of technological characteristics of the device compared to the predicate device. These blood pressure/pulse rate meters are intended to be used in measuring human systolic, diastolic and pulse rate by oscillometric (or manual) method. Performance characteristics are in accordance with ANSI/AAMI SP10:2002/(R) 2008. 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 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 60601-1-6:2010, +AMD1:2013, General requirements for safety - Collateral Standard: Usability FDA recognition 5-89

   IEC 60601-1-11:2015, MEDICAL ELECTRICAL EQUIPMENT -Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment FDA recognition 19-14 (Applies only to models BP170; BP170B; BP160; BP160B)

   IEC 80601-2-30:2009, +AMD1:2013 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers FDA recognition 3-152

   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

IEC 62304 [2006] Medical device software, Software life-cycle processes FDA recognition 13-79

8. Clinical Testing: Successful testing was performed according to ANSI/AAMI SP10 : 2002/ (R) 2008 & ANSI/AAMI SP10 : 202/A1 : 2003/ (R) 2008 and the FDA Guidance Document. The SP10 standard calls for a minimum of 85 subjects using a minimum of 255 paired observations, comparing to a manual blood pressure measurement. Separate clinical investigations were performed for the BP170 Series and the BPBIO250. For the BP170, 106 subjects were tested. For the BPBIO250, 104 subjects with 312 observations were tested. The criteria for the acceptance of the overall system accuracy follow the SP10 requirements:
   a) maximum mean error of measurement: 5mmHg
   b) maximum experimental standard deviation: 8mmHg

   InBody has compared the accuracy between mercury manometer using the stethoscope and the non-invasive automatic sphygmomanometers. We found and concluded that they are substantially equal to each other.

9. Conclusion, Comparison to the predicate device. Proposed Models: BP170; BP170B; BP160; BP160B; BPBIO250 are substantially equivalent to the BPBIO320/BPBIO320n whose 510(k) number is K131064. The devices are identical in the intended use, and very similar in the design principles, the performance and the applicable standards. Only their appearance, use of an external blood pressure cuff, and the user interfaces are different.