510(k) Summary K130777

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***DATE PREPARED:* February 15, 2013**
Contact: Kichul Cha, CEO

1. Identification of the Devices:

Proprietary-Trade Names:

- Biospace Body Composition Analyzer, Model InBody 120
- Biospace Body Composition Analyzer, Model InBody 370
- Biospace Body Composition Analyzer, Model InBody 720
- Biospace Body Composition Analyzer, Model InBody 520

Classification Names: ANALYZER, BODY COMPOSITION
Common/Usual Name: Body fat meter
Regulation Description: Impedance plethysmograph.
Classification Panel: Cardiovascular
Product Code: MNW
Regulation Number: 870. 2770
Classification: II

2. Equivalent legally marketed devices: (Predicate device Information)

Biospace Body Composition Analyzer Model InBody 170, InBody J30 InBody S10, K110689
The Segmental Body Water indication was cleared in K123228, InBody 770, InBody570, InBodyS10, InBody H20.

3. Indications for Use:

For use only in healthy subjects for Measurement of:

Estimated: Skeletal Muscle Mass, Extra-Cellular Water (ECW), Intra-Cellular Water (ICW), Total Body Water (TBW), ECW/TBW, Body Fat, Percentage of Body Fat (PBF), Body Lean + Dry Lean, Metabolic Rates(Basal Metabolic Rates), Segmental Lean Mass, Segmental Fat Mass, % Segmental Body Fat, Energy Expenditure of Activity, Visceral Fat Area (VFA), Visceral Fat Level, Segmental Body Water, Percent Body Water, Body Shape Graph, Weight Control, Fat Control, Muscle Control

Actual: Weight, Body Mass Index (BMI) and Impedance Values, Height [which can require the entry of Height], Resistance Values [only for InBody720], Reactance Values [only for InBody720], Phase Angle [only for InBody720]

4. Description: These devices are impedance plethysmograph body composition analyzers. These devices determine body composition parameters based on bioelectrical impedance analysis (BIA). BIA relies on the differing behavior of biological tissues in response to an applied electrical current. Lean tissue is generally highly conductive because it contains large amounts of bound water and electrolytes, while fat tissue and bone are relatively poor conductors. By analyzing the response to electrical signals, BIA thereby permits differentiation of lean tissue, fat, and water and, in some instances, derivation of related body composition parameters. The total impedance resulting from BIA incorporates both resistance and capacitance components. Impedance plethysmographic devices are used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs. Multi-frequency and segmental bioelectrical impedance analysis can estimate the distribution of body water (total body water; intra-cellular water; extra-cellular water), and can correlate with fluid compartmentalization. Assuming that body lean mass is hydrated in a constant and uniform manner; bioelectrical impedance analysis can be used to estimate body lean mass and fat mass. Body composition analysis results may be of value to health care professionals in their management of the relative balance and levels of fat and lean tissue

5. Safety and Effectiveness, comparison to predicate device. The results of bench, safety, and software testing indicates that the new devices are as safe and effective as the predicate device.

6. Comparison table

Devices		**InBody 170**	**InBody J30**	**InBody S10**	**InBody 120**	**InBody 370**	**InBody 720**	**InBody 520**
510(k) number		K110689	K110689	K110689	New	New	New	New
Manufacturer		Biospace	Biospace	Biospace	Biospace	Biospace	Biospace	Biospace
Measurement of Estimated :	Extra-Cellular Water (ECW)	√	√	√		√	√	√
	Intra-Cellular Water (ICW)	√	√	√		√	√	√
	Total Body Water (TBW)	√	√	√	√	√	√	√
	Skeletal Muscle Mass	√	√	√	√	√	√	√
	Body Fat Mass	√	√	√	√	√	√	√
	Lean Body Mass	√	√	√	√	√	√	√
	Dry Lean Mass	√	√	√		√	√	√
	Basal Metabolic Rates	√	√	√	√	√	√	√
	Segmental Lean Mass	√	√	√	√	√	√	√
	ECW/TBW	√	√	√		√	√	√
	Segmental Body Fat	√	√	√		√		

Devices		InBody 170	InBody J30	InBody S10	InBody 120	InBody 370	InBody 720	InBody 520
	mass							
	% Segmental Body Fat	√	√	√				
	Energy expend-iture of activity	√	√	√				
	Visceral Fat Area	√	√	√				
	Segmental Body Water	(Cleared in K123228)	(Cleared in K123228)	(Cleared in K123228)	√	√	√	√
Measure-ment of Actual :	**Weight**	√	√		√	√	√	√
	Height		√		√	√	√	√
	Body Mass Index (BMI)	√	√	√	√	√	√	√
	Impedance Values	20, 100kHz	5, 50, 250kHz	1, 5, 50, 250, 500, 1,000kHz	20, 100kHz	5, 50, 250kHz	1, 5, 50, 250, 500, 1,000kHz	5, 50, 500 kHz
	Reactance Values			5, 50, 250kHz			5, 50, 250kHz	
	Phase Angle			5, 50, 250kHz			5,50,250k Hz	
Measurement method		**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**	**Bioelectrical Impedance**
Electrode type		**4 electric poles 8 points Touch type electrode measure-ment**	**4 electric poles 8 points Touch type electrode measure-ment**	**4 electric poles 8 points Touch type electrode measure-ment**	**4 electric poles 8 points Touch type electrode measurement**	**4 electric poles 8 points Touch type electrode measure-ment**	**4 electric poles 8 points Touch type electrode measure-ment**	**4 electric poles 8 points Touch type electrode measure-ment**
Power Source		Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60 Hz, 1.2A Output power: DC12V, 3.4A	Input power: AC 100-120/200-240V, 50/60Hz, 1.2A Output power: DC12V, 3.4A	100-240V~, 50/60Hz No adapter	Input power: AC 100-120/200-240V, 50/60Hz, 1.2A Output power: DC12V, 3.5A
Equipment weight		14.3kg	29kg	2kg	5.7kg	20 kg	45kg	26kg
Equipment size		396(W) x 608(L) x 955(H) :	360(W) x 640(L) x 2235(H) :	202(W) x 322(L) x 53(H): mm	393(W) x 516(L) x 732(H) : mm	460(W) x 677(L) x 1020(H):	520(W) x 870(L) x 1200(H):	522 (W) x 843(L) x 1015(H) :

Devices	InBody 170	InBody J30	InBody S10	InBody 120	InBody 370	InBody 720	InBody 520
	mm	mm			mm	mm	mm
Measurement time	30 seconds	30 seconds	110 seconds	Weight measure-ment 3~5 seconds, Impedance measure-ment 5~7 seconds.	45 seconds	Less than 1 minute for medical mode(Less than 2 minutes for research purpose mode)	50 seconds
Measurement age	From age 3 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99	From age 3 ~ age 99
Measurement weight	10 ~ 250kg	10 ~ 250kg	10 ~ 250kg	5 ~ 250kg	10 ~ 250kg	10 ~ 250kg	10 ~ 250kg

7. Discussion of Non-Clinical Testing: Electromagnetic and Safety Testing was conducted to IEC 60601-1 and IEC 60601-1-2. Software validation was conducted. Literature was compiled and reviewed.

8. Discussion of Clinical Testing:
In order to verify InBody120's clinical performance, we conducted comparison performance test between InBody120 and InBody720 that obtained FDA premarket notification under FDA law. The test was conducted from August 19rd, 2012 to August 23th, 2012 with a group of 39 examinees.
In order to verify InBody370's clinical performance, we conducted comparison performance test between InBody370 and InBody720 that obtained FDA premarket notification under FDA law. The test was conducted from September 3rd, 2012 to September 5th, 2012 with a group of 88 examinees.
In order to verify InBody520's clinical performance, we conducted comparison performance test between InBody520 and InBody J30 that obtained FDA premarket notification under FDA law. The test was conducted from July 2nd, 2010 to July 4th, 2010 with a group of 75 examinees.
In order to verify InBody 720's clinical performance, we conducted comparison performance test between InBody J30 and InBody720 that obtained FDA premarket notification under FDA law. The test was conducted from July 2nd, 2010 to July 4th, 2010 with a group of 62 examinees

9. Conclusion: As compared to our predicate devices (our own brand) these new models have very similar technological characteristics and performed comparably to our predicates. The same scientific principles are used to produce the measurements. We therefore conclude that our new models are substantially equivalent to our predicates cleared in 2011.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25, 2013

Biospace Corporation Limited
% Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
8870 Ravello Ct
Naples, FL 34114

Re: K130777
Trade/Device Name: Biospace Body Composition Analyzer, Model InBody120
Biospace Body Composition Analyzer, Model InBody 370
Biospace Body Composition Analyzer, Model InBody 720
Biospace Body Composition Analyzer, Model InBody 520
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: October 28, 2013
Received: October 30, 2013

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130777

Device Names:
1) Biospace Body Composition Analyzer, Model InBody120
2) Biospace Body Composition Analyzer, Model InBody370
3) Biospace Body Composition Analyzer, Model InBody720
4) Biospace Body Composition Analyzer, Model InBody520

Indications for use:

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Estimated: Skeletal Muscle Mass, Extra-Cellular Water (ECW), Intra-Cellular Water (ICW), Total Body Water (TBW), ECW/TBW, Body Fat, Percentage of Body Fat (PBF), Body Lean + Dry Lean, Metabolic Rates(Basal Metabolic Rates), Segmental Lean Mass, Segmental Fat Mass, % Segmental Body Fat, Energy Expenditure of Activity, Visceral Fat Area (VFA), Visceral Fat Level, Segmental Body Water, Percent Body Water, Body Shape Graph, Weight Control, Fat Control, Muscle Control

Actual: Weight, Body Mass Index (BMI) and Impedance Values, Height [which can require the entry of Height], Resistance Values [only for InBody720], Reactance Values [only for InBody720], Phase Angle [only for InBody720]

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____X____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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