510(k) Summary K110689

AUG 19 2011

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July 11, 2011
Contact: Kichul Cha, CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: Biospace Body Composition Analyzers, InBodyS10; InBody170; InBodyJ30;
   Classification Names: MNW ANALYZER, BODY COMPOSITION
   Common/Usual Name: Body fat meter

2. **Equivalent legally marketed devices:** The BioSpace InBodyS20(K052646) and The BioSpace InBody270(K092786)

3. **Indications for Use (intended 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), Body Fat, Body Lean + Dry Lean, Metabolic Rates, Segmental Lean Mass, Segmental Body Fat mass, % Segmental Body Fat, and Energy expenditure of activity, Visceral Fat Area (VFA).
   Actual : Weight [except for model S10, which requires the manual entry of weight], Body Mass Index (BMI), Impedance Values, height [only for model InBodyJ30, which has height-meter function].

4. **Description of the Device:** InBodyS10, InBody170, and InBodyJ30 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.

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

6. **Substantial Equivalence Chart,** InBodyS10; InBody170; InBodyJ30; (Next page)

Devices		InBody270	InBodyS20	InBodyS10	InBody170	InBodyJ30
510(k) number		K092786	K052646	New	New	New
Manufacturer		BioSpace	BioSpace	BioSpace	BioSpace	BioSpace
Measurement of Estimated :	Extra-Cellular Water(ECW),	√	√	√	√	√
	Intra-Cellular Water(ICW),	√	√	√	√	√
	Total Body Water,	√	√	√	√	√
	Skeletal Muscle Mass	√		√	√	√
	Body Fat,	√	√	√	√	√
	Body Lean + Dry Lean,	√	√	√	√	√
	Basal Metabolic Rates,	√	√	√	√	√
	Segmental Lean Mass,	√	√	√	√	√
	ECW/TBW		√	√	√	√
	Segmental Body Fat mass,	√		√	√	√
	% Segmental Body Fat,	√		√	√	√
	Energy expenditure of activity,	√		√	√	√
	Visceral Fat Area (VFA)			√ (Evaluation with CT)	√ (Evaluation with CT)	√ (Evaluation with CT)
Measurement of Actual :	Weight	√			√	√
	height					√ (Predicate BSM370_ scale, stand-on, patient, 510(k) exempt)
	Body Mass Index (BMI),	√	√	√	√	√
	Impedance Values:	20, 100kHz	1, 5, 50, 250, 500, 1,000kHz	1, 5, 50, 250, 500, 1,000kHz	20, 100kHz	5, 50, 250kHz
	Reactance Values:		5,50,250kHz	5,50,250kHz		
Analysis Method	Bioelectrical Impedance	√	√	√	√	√
Electrode Type	Tactile	√			√	√
	Tactile / Adhesive		√	√		
Number of Electrodes	8 electrodes	√	√	√	√	√
Placement of Electrodes	placed on thumbs	√	√	√	√	√
	placed on palms,	√	√	√	√	√
	placed on heels	√	√	√	√	√
	placed on fore-feet	√	√	√	√	√
Electrode connection geometry	First and third finger		√	√		
	ankle		√	√		
	Hand	√			√	√
	Foot	√			√	√
Impedance Measuring Site	Right Arm	√	√	√	√	√
	Left Arm	√	√	√	√	√
	Trunk	√	√	√	√	√
	Right Leg	√	√	√	√	√
	Left Leg	√	√	√	√	√
Patient Position	Upright	√			√	√
	Supine		√	√		

Devices		InBody270	InBodyS20	InBodyS10	InBody170	InBodyJ30
	Sitting			√		
Application software (Optional)	LB 110 (Stand-alone device)			√ (510(k) Exempt)	√ (510(k) Exempt)	√ (510(k) Exempt)

7. Conclusion

After analyzing bench testing data, software validation, and the risk analysis, and based upon the intended use, and upon the similarity of product configuration and administration, it can be concluded that Model InBodyS10, InBody170, InBodyJ30 are substantially equivalent to the identified predicate devices in terms of intended use, safety and effectiveness. The safety characteristics are identical to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Biospace Corporation Limited
% Mr. Daniel Kamm, P.E.
Principal Consultant
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AUG 19 2011

Re: K110689
Trade/Device Name: InBodyS10, InBody170, InBodyJ30
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: August 12, 2011
Received: August 17, 2011

Dear Mr. 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, M.D., Director (Acting)
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) : K110689

Device Name : InBodyS10, InBody170, InBodyJ30

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), Body Fat, Body Lean + Dry Lean, Metabolic Rates, Segmental Lean Mass, Segmental Body Fat mass, % Segmental Body Fat, and Energy expenditure of activity, Visceral Fat Area (VFA).

Actual : Weight [except for model S10, which requires the manual entry of weight], Body Mass Index (BMI), Impedance Values, height [only for model InBodyJ30, which has height-meter function]

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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K110689