510(k) Summary

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FEB 15 2007

January 15, 2006
Contact: Kichul Cha, CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: Biospace Body Composition Analyzers, Model Inbody 230
   Classification Names: 74 MNW ANALYZER, BODY COMPOSITION
   Common/Usual Name: Body fat meter

2. **Equivalent legally marketed devices:** Biospace Body Composition Analyzer Model InBody 3.0, K042528, Model InBody 520, K052646. Predicates for skeletal muscle mass are: Tanita Ironman Innerscan Body Composition Monitor Model BC-558 (K062652 and Omron Body Composition Monitor and Scale Model HBF-500 (K062043)

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.
   Actual : Weight, Body Mass Index (BMI),and Impedance Values

4. **Description of the Device:** Model Inbody 230 is an impedance plethysmograph body composition analyzer. This device determines 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 clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart,** Model Inbody 230 BODY COMPOSITION ANALYZER

	Biospace Body Composition Analyzer Model InBody 3.0	Biospace Body Composition Analyzer Model InBody 520	Biospace Body Composition Analyzer Model InBody 230
510(k) number	K042528	K052646	(NEW)
Intended Use	Body composition analyzer	Body composition analyzer	Body composition analyzer
Indications for Use	Measurement Of: Estimated : Extra-Cellular Water(ECW), Intra-Cellular Water(ICW), Total Body Water, ECW/TBW Body Fat, Body Lean + Dry Lean, Metabolic Rates, Segmental Lean Mass Actual : Weight, Body Mass Index (BMI), and Impedance Values: 5, 50, 250, 500kHz	Measurement Of: Estimated : Extra-Cellular Water(ECW), Intra-Cellular Water(ICW), Total Body Water, ECW/TBW Body Fat, Body Lean + Dry Lean, Metabolic Rates, Segmental Lean Mass Actual : Weight, Body Mass Index (BMI), and Impedance Values: 5, 50, 500kHz	Measurement Of: Estimated : Extra-Cellular Water(ECW), Intra-Cellular Water(ICW), Total Body Water, Skeletal Muscle Mass Body Fat, Body Lean + Dry Lean, Metabolic Rates, Segmental Lean Mass Actual : Weight, Body Mass Index (BMI), and Impedance Values: 20, 100kHz
Analysis Method	Bioelectrical Impedance	Bioelectrical Impedance	Bioelectrical Impedance
Operating parameters	Frequency : 5, 50, 250, 500kHz	Frequency : 5, 50, 500kHz	Frequency : 20, 100kHz
Electrode Type	tactile	tactile	Tactile
Number / Placement of Electrodes	8 electrodes placed on thumbs, palms, heels, and fore-feet	8 electrodes placed on thumbs, palms, heels, and fore-feet	8 electrodes placed on thumbs, palms, heels, and fore-feet
Impedance Measuring Site	Right Arm, Left Arm, Trunk, Right Leg, Left Leg	Right Arm, Left Arm, Trunk, Right Leg, Left Leg	Right Arm, Left Arm, Trunk, Right Leg, Left Leg
Patient Position	Upright	Upright	Upright
Power Source	AC line	SAME	SAME

7. **Conclusion**

After analyzing both bench and clinical testing data, it is the conclusion of Biospace that the Model Inbody 230, BODY COMPOSITION ANALYZER is as safe and effective as the predicate devices, and has few technological differences, thus rendering it substantially equivalent to the predicate devices. The change in testing frequencies has been validated via human clinical trial.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Biospace Corporation Ltd.
c/o Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

FEB 15 2007

Re: K062603
Trade/Device Name: Biospace Body Composition Analyzer, Model InBody 230
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: January 28, 2007
Received: January 31, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062603

Device Name: Biospace Body Composition Analyzer, Model Inbody 230

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,

Actual : Weight, Body Mass Index (BMI),and Impedance Values

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (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 K062603