510(k) Summary K09

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MAR 1 0 2010

August 27, 2009
Contact: Kichul Cha, CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: Biospace Body Composition Analyzers, Models InBody 270, InBody R20, and InBody R20B
   Classification Names: 74 MNW ANALYZER, BODY COMPOSITION
   Common/Usual Name: Body fat meter

2. **Equivalent legally marketed devices:** Biospace Body Composition Analyzer Model InBody 230 K062603

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

4. **Description of the Device:** Models InBody 270, InBody R20, and InBody R20B 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, Model InBody 270, InBody R20, and InBody R20B .

	Biospace Body Composition Analyzer Model InBody 230	Models InBody 270, InBody R20, and InBody R20B
510(k) number	K062603	(NEW)
Indications for Use	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 Measurement of Actual : Weight Body Mass Index (BMI) Impedance Values	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 New: Segmental Body Fat mass % Segmental Body Fat- Energy expenditure of activity Measurement of Actual : Weight Body Mass Index (BMI) Impedance Values
Analysis Method	Bioelectrical Impedance	Bioelectrical Impedance
Operating parameters	Frequency : 20, 100kHz	Frequency : 20, 100kHz
Electrode Type	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
Impedance Measuring Site	Right Arm, Left Arm, Trunk, Right Leg, Left Leg	Right Arm, Left Arm, Trunk, Right Leg, Left Leg
Patient Position	Upright	Upright
Patient population	Healthy individuals	SAME
Power Source	AC Line	SAME, Except Model R20 operates from 4-AA alkaline batteries.

Differences between models InBody 270, InBody R20, and InBody R20B:
InBody 270 has a pedestal stand for the hand contacts, and InBody R20/R20B use a coiled cord for the hand contacts. Model R20B has Bluetooth, whereas the other two models do not.

7. Conclusion

After analyzing bench testing data, software validation, and the risk analysis, it is the conclusion of Biospace that the Models InBody 270, InBody R20, and InBody R20B, BODY COMPOSITION ANALYZERS are as safe and effective as the predicate devices, and have few technological differences, thus rendering them substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

Biospace Corporation Ltd.
c/o Mr. Daniel Kamm
Kamm & Associates
8726 Ferrara Court
NAPLES FL 34114

MAR 10 2010

Re: K092786
Trade/Device Name: Biospace Body Composition Analyzer, Models InBody 270, InBody R20, and InBody R20B
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: January 26, 2010
Received: February 2, 2010

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,

Janine M. Morris
Acting 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): K092786

Device Name: Biospace Body Composition Analyzer, Models InBody 270, InBody R20, and InBody R20B.

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.

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 K092786

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