JAN 1 1 2005

EXHIBIT 2

510(k) Summary

Biospace Corporation Limited
363 Yangjae-dong, Seocho-gu, Seoul 137-898, Korea
Tel : +82-2-501-3939,
Fax : +82-2-501-3978
Homepage : http:// www.biospace.co.kr

November 8, 2004

Contact: Kichul Cha, CEO

1. **Identification of the Device:**
   Proprietary-Trade Name: InBody AP1 BODY COMPOSITION ANALYZER
   Classification Names: 74 MNW ANALYZER, BODY COMPOSITION
   Common/Usual Name: Body fat meter

2. **Equivalent legally marketed devices:** K002835 BodyStat QuadScan 4000; K830292 RJL Systems BIA-101A; K023478 Biospace Body Composition Analyzer Model InBody AP1

3. **Indications for Use (intended use)** For use only in healthy subjects for Measurement Of: Estimated : Extra-Cellular Water (ECW), Intra-Cellular Water (ICW),Total Body Water (TBW), ECW to TBW ratio, 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:** InBody 3.0 is an impedance plethysmograph body composition analyzer. The 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, InBody AP1 BODY COMPOSITION ANALYZER

	BodyStat QuadScan 4000	RJL Systems BIA-101A	Biospace Body Composition Analyzer Model InBody AP1	Biospace Body Composition Analyzer Model InBody 3.0
510(k) number	K002835	K830292	K023478	
Intended Use	Body composition analyzer	Body composition analyzer	Body composition analyzer	Body composition analyzer
Indications for Use (Healthy subjects)	Measurement Of: Estimated : Extra-Cellular Water, Intra-Cellular Water, Total Body Water, Body Fat, Body Lean + Dry Lean, Metabolic Rates, Actual : Waist/Hip Ratio, Body Mass Index (BMI), and Impedance Values: 5, 50, 100, 200kHz	Measurement Of: Resistance and Reactance Value: 50kHz	Measurement Of: Estimated : Extra-Cellular Water, Intra-Cellular Water, Total Body Water, Body Fat, Body Lean + Dry Lean, Metabolic Rates, Actual : Weight, Body Mass Index (BMI), and Impedance Values: 5, 50, 250kHz	Measurement Of: Estimated : Extra-Cellular Water(ECW), Intra-Cellular Water(ICW), Total Body Water (TBW), ECW to /TBW ratio Body Fat, Body Lean + Dry Lean, Metabolic Rates, Segmental Lean Mass Actual : Weight, Body Mass Index (BMI), and Impedance Values: 5, 50, 250, 500kHz
Analysis Method	Bioelectrical Impedance	Bioelectrical Impedance	Bioelectrical Impedance	Bioelectrical Impedance
Operating parameters	Frequency : 5, 50, 100, 200kHz	Frequency : 50kHz	Frequency : 5, 50, 250kHz	Frequency : 5, 50, 250, 500kHz
Electrode Type	adhesive	adhesive	tactile	tactile
Number / Placement of Electrodes	4 electrodes placed on hands and feet	4 electrodes placed on hands and feet	8 electrodes placed on thumbs, palms, heels, and fore-feet	8 electrodes placed on thumbs, palms, heels, and fore-feet
Impedance Measuring Site	Whole Body (Right Arm to Right Leg)	Whole Body (Right Arm to Right Leg)	Right Arm, Left Arm, Trunk, Right Leg, Left Leg	Right Arm, Left Arm, Trunk, Right Leg, Left Leg
Patient Position	Supine	Supine	Upright	Upright

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of Biospace that the InBody 3.0 BODY COMPOSITION ANALYZER as safe and effective as the predicate devices, and has few technological differences, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2005

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

Re: K042528
Trade/Device Name: InBody 3.0 Body Composition Analyzer
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: November 8, 2004
Received: November 9, 2004

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 (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); 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/dsma/dsmamain.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): K042528

Device Name: Biospace InBody 3.0

Indications For Use:

For use only in healthy subjects for Measurement Of:
Estimated : Extra-Cellular Water (ECW), Intra-Cellular Water (ICW),Total Body Water (TBW), ECW to TBW ratio, 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)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042528

Page 1 of 1