K023478
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MAY 1 3 2003

EXHIBIT 2

510(k) Summary of Safety and Effectiveness

Biospace Corporation Limited
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Homepage : http:// www.biospace.co.kr

October 2, 2002
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** BodyStat QuadScan 4000, K002835, RJL Systems BIA-101A, K830292, Tanita Corporation of America Body Fat Analyzer Model TBF-105, K930599, and Omron Healthcare Body Fat Analyzer Model HBF-306, K011652.

3. **Indications for Use (intended use)** For 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.

4. **Description of the Device:** InBody AP1 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	Biospace Body Composition Analyzer Model InBody AP1
510(k) number	K002835	
Intended Use	Body composition analyzer	Body composition analyzer
Indications for Use	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	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
Analysis Method	Bioelectrical Impedance	Bioelectrical Impedance
Operating parameters	Frequency : 5, 50, 100, 200kHz	Frequency : 5, 50, 250kHz
Electrode Type	adhesive	tactile
Number / Placement of Electrodes	4 electrodes placed on hands and feet	8 electrodes placed on thumbs, palms, heels, and fore-feet
Impedance Measuring Site	Whole Body (Right Arm to Right Leg)	Right Arm, Left Arm, Trunk, Right Leg, Left Leg
Patient Position	Supine	Upright

7. **Conclusion**

After analyzing both bench and clinical testing data, it is the conclusion of Biospace that the InBody AP1 BODY COMPOSITION ANALYZER as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, 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

MAY 13 2003

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

Re: K023478
Trade/Device Name: Biospace InBody, Model AP1, Body Composition Analyzer
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: February 11, 2003
Received: February 12, 2003

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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

j) Indications for Use

510(k) Number K023478

Device Name: InBody AP1 BODY COMPOSITION ANALYZER

Indications for Use: For 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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023478