MAR 2 0 2008

510(k) Summary K073227

AIIA Communication Inc.
Geumwon building, #714-1, Bokjung-dong, Sujung-gu, Sungnam-si, Gyunggi-do, Korea
Tel : +82-31-751-3697
Fax : +82-31-751-2648
Homepage : http://www.aiia.co.kr

March 10, 2007

Contact: Ho Lee, R&D Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: SLIMMANAGER, Body composition analyzer (Models: N40, SM-300).
   Classification Names: 74 MNW ANALYZER, BODY COMPOSITION
   Common/Usual Name: Body composition analyzer

2. **Equivalent legally marketed devices** Biospace InBody 230 K062603; AIIA communication Inc. SLIMMANAGER(SM-X, SM-E) K051589

3. **Indications for Use (intended use) (Models SM-300 and N40)** For Measurement in healthy subjects of: Estimated : ECW, ICW, TBW, ECW/TBW, Body Fat, Body Lean +Dry Lean Metabolic Rates, Segmental Lean Mass. Model N40 adds: Skeletal Muscle Mass; Actual: Weight, BMI, Impedance Values

4. **Description of the Device:** SLIMMANAGER is a body composition analyzer and uses Bioelectrical Impedance Analysis technology to determine body composition parameters. Using a principle that an electric current has a low impedance when it flows in muscle or cellular fluids containing lots of water while it has a high impedance such as in fat and bone tissues slowing and stopping an applied current, BIA sends an extremely weak electric current through the body and detects the relative response after it flows our body's various substances, and then it can determines lean tissue, fat, water mass. All measurements made by SLIMMANAGER can be recorded & saved in the website real-time by the Internet transmission as well in the device, and in his own page people could check their changing progress even a minute change without an expert's advice at anywhere, at anytime. N-40 is designed by Linux system with touch monitor, while SM-300 should be interfaced with customer's PC.

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,** SLIMMANAGER, Body composition analyzer (Models: N40, SM-300).

Company	**Biospace**	**AIIA communication Inc.**	**AIIA communication Inc.**	**AIIA communication Inc.**
Model	InBody 230	SLIMMANAGER(SM-X, SM-E)	SLIMMANAGER(N40)	SLIMMANAGER(SM-300)
510(k) no.	K062603	K051589	New	New
Method	**B**ioelectrical **I**mpedance **A**nalysis	**B**ioelectrical **I**mpedance **A**nalysis	**B**ioelectrical **I**mpedance **A**nalysis	**B**ioelectrical **I**mpedance **A**nalysis
Electrode	8 electrodes	8 electrodes	8 electrodes	8 electrodes
Type	tactile	tactile	tactile	tactile
Intended Use	Estimated : ECW, ICW, TBW ECW/TBW Body Fat Body Lean +Dry Lean Metabolic Rates Segmental Lean Mass Skeletal Muscle Mass Actual : Weight BMI Impedance Values	Estimated : ECW, ICW, TBW ECW/TBW Body Fat Body Lean +Dry Lean Metabolic Rates Segmental Lean Mass Actual : Weight BMI Impedance Values	Estimated : ECW, ICW, TBW ECW/TBW Body Fat Body Lean +Dry Lean Metabolic Rates Segmental Lean Mass Skeletal Muscle Mass Actual : Weight BMI Impedance Values	Estimated : ECW, ICW, TBW ECW/TBW Body Fat Body Lean +Dry Lean Metabolic Rates Segmental Lean Mass Actual : Weight BMI Impedance Values
Frequency	20, 100KHz	5, 50, 250, 500KHz	500Hz, 50, 500KHz	50KHz
Measuring scope	10 ~ 250 kg	1 ~ 250 kg	1 ~ 200 kg	1 ~ 150 kg
Position	Upright	Upright	Upright	Upright
Display	240x320 STN LCD	1024x768 Color TFT Touch Screen LCD / PC interface (SM-E model)	640x480 Color TFT Touch Screen LCD	PC interface
Power	AC100~120/200~240V	AC100~120/200~240V	AC100~120/200~240V	AC100~120/200~240V

7. Conclusion

After analyzing both bench and clinical testing data, it is the conclusion of AIIA Communication Inc.that the SLIMMANAGER, Body composition analyzer (Models: N40, SM-300). 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

MAR 2 0 2008

AIIA Communication Inc.
c/o Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K073227
Trade/Device Name: SLIMMANAGER, Body composition analyzer (Models N40, SM-300)
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: March 10, 2008
Received: March 13, 2008

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 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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): K073227

Device Name: SLIMMANAGER, Body composition analyzer (Models N40, SM-300)

Indications For Use: For Measurement in healthy subjects of:

Estimated : ECW, ICW, TBW, ECW/TBW, Body Fat, Body Lean +Dry Lean Metabolic Rates, Segmental Lean Mass. Model N40 adds: Skeletal Muscle Mass
Actual : Weight, BMI, 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
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