K071884
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Attachment 4

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510(k) Summary

[As Required by 21 CFR 807.92]

Date Prepared: July 05, 2007

Submitter:

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Contact Person:

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Trade Name: Body Composition Analyzer
Models X-SCAN PLUS II, GAIA 359 PLUS, PLUSAVIS 333, XBIA 500 and XBIA 900

Common Name: Body Fat Analyzer / Body Fat Monitor / Body Composition Monitor

Classification Name: Body Composition Analyzer (Impedance plethysmograph) / MNW

Predicate Device: Body Composition Analyzer Models VENUS 5.5 and ZEUS 9.9 (K053556)

Device Description: The X-SCAN PLUS II, GAIA 359 PLUS, PLUSAVIS 333, XBIA 500 and XBIA 900 are body composition analyzers intended for use only in healthy subjects between the age of 7-89. The devices employ BIA(Bio-electrical Impedance Analysis) method and 8 electrodes placed on hands and feet (or ankles), and then measure body composition using an experimentally derived algorithm. For only XBIA 500, optional ankle electrode is not supplied. The devices are powered by AC100~230V 50/60Hz.

Intended use: These devices are intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), TBW(Total Body Water),

BMI(Body Mass Index), BMR(Basic Metabolic Rate), Segmental LBM, ICW(Intra-Cellular Water), ECW(Extra-Cellular Water), and ratio of ECW/TBW using the BIA(Bio-electrical Impedance Analysis) method. The device measures or calculates the impedance, BMI(Body Mass Index), weight, and WHR(Waist to Hip Ratio) of the user.

These devices are intended for use only in healthy subjects between the age of 7-89.

Technologic characteristics: Modified devices X-SCAN PLUS II, GAIA 359 PLUS, PLUSAVIS 333, XBIA 500 and XBIA 900 have the same intended use and technology characteristics as predicate devices VENUS 5.5 and ZEUS 9.9. The differences in this submission don't raise new questions concerning either safety or effectiveness.

Non-clinical and clinical tests: Modified devices X-SCAN PLUS II, GAIA 359 PLUS, PLUSAVIS 333, XBIA 500 and XBIA 900 meet the requirements of IEC 60601-1, EN 60601-1-2 and in-house test criteria. The results of clinical comparison tests with predicate device ZEUS 9.9 demonstrate that there is no significant difference between the modified devise and the predicate device.

Conclusions: Based on non-clinical and clinical tests, the modified devices X-SCAN PLUS II, GAIA 359 PLUS, PLUSAVIS 333, XBIA 500 and XBIA 900 are as safe, as effective, and perform as well as the predicate devices VENUS 5.5 and ZEUS 9.9. Accordingly the modified devices are substantially equivalent to the predicate devices.

< Differences between predicate devices and modified devices >

Item	VENUS 5.5/ZEUS 9.9	X-SCAN PLUS II	GAIA 359 PLUS	PLUSAVIS 333	XBIA 500	XBIA 900
510(k) #	K053556	Modified device	Modified device	Modified device	Modified device	Modified device
Number/ Placement of Electrodes	8 electrodes placed on hands and feet (or ankle) (Tetra-polar electrode method)	Same	Same	Same	8 electrodes placed on hands and feet (Tetra-polar electrode method)	Same
Operating parameters	Frequency: 1,5, 50, 250,550,1000kHz	Same	Frequency: 5, 50, 250kHz	Frequency: 5, 50, 250kHz	Frequency: 5, 50, 250kHz	Same
Electrical current applied during measurement	Maximum current 360uA	Maximum current 180uA	Maximum current 500uA	Maximum current 500uA	Maximum current 280uA	Maximum current 280uA
Power consumption	50VA	70VA	40VA	40VA	40VA	70VA
Power supply	AC120V 50/60Hz	AC100~230V 50/60Hz	AC100~230V 50/60Hz	AC100~230V 50/60Hz	AC100~230V 50/60Hz	AC100~230V 50/60Hz
Input height	110 ~ 200 cm	110 ~ 200 cm	100 ~ 200 cm	100 ~ 200 cm	100 ~ 200 cm	80 ~ 200 cm
Display LCD	Digital LCD (640 x 480 pixel) – black	Digital LCD (6.4", 800 x 600 pixel) - color	Digital LCD (6.4", 640 x 480 pixel) - color	Digital LCD (6.4", 480 x 320 pixel) - black	Digital LCD (6.4", 640 x 480 pixel) - color	Digital LCD (12.1", 800 x 600 pixel) - color
Protocol connecting to PC	RS-232C (9 pin serial port), USB port	USB port	USB port	USB port	USB port	USB port
	None	Bluetooth Function	None	None	None	Bluetooth Function
Protocol connecting to printer	IEEE 1284(25pin parallel) port printer or PCB 3 protocol supplied printer	IEEE 1284(25pin parallel) port	USB port	USB port, Thermal printer	USB port	USB port
'Blood Pressure' port	None	Yes	Yes	Yes	Yes	Yes
Dimensions (W x D x H; Unit: mm)	470 x 655 x 1220	496 x 836 x 1150	460 x 660 x 1000	460 x 660 x 1000	400 x 673 x 972	476 x 848 x 1062
Weight(main unit)	45kg	45kg	24kg	24kg	24kg	45kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG - 9 2007

Jawon Medical Co., Ltd.
c/o Mr. HL Jung, Manager
MI Consulting Co., Ltd.
Room 624, LifeOfficetel 61-3
Yoido-dong, Youngdeungpo-gu, Seoul 150-731
REPUBLIC OF KOREA

Re: K071884
Trade/Device Name: Body Composition Analyzers – Models X-SCAN PLUS II, GAIA 359 PLUS, PLUSAVIS 333, XBIA 500, & XBIA 900
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: July 5, 2007
Received: July 10, 2007

Dear Mr. Jung:

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

Attachment 1

Indications for Use Statement

510(k) Number (if known): K071884

Device Name: Jawon Medical Body Composition Analyzer
Models X-SCAN PLUS II, GAIA 359 PLUS, PLUSAVIS 333, XBIA 500 and XBIA 900

Indications for Use:
These devices are intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), TBW(Total Body Water), BMI(Body Mass Index), BMR(Basic Metabolic Rate), Segmental LBM, ICW(Intra-Cellular Water), ECW(Extra-Cellular Water), and ratio of ECW/TBW using the BIA(Bio-electrical Impedance Analysis) method. The device measures or calculates the impedance, BMI(Body Mass Index), weight, and WHR(Waist to Hip Ratio) of the user.
These devices are intended for use only in healthy subjects between the age of 7-89.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE NO 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 K071884