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Section 5

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510(k) Summary

[As Required by 21 CFR 807.92]

Date Prepared: August 03, 2007

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Trade Name: Body Composition Analyzer
Models EasyBody 202, EasyBody 203 and EasyBody 205

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

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

Predicate Device: Body Composition Analyzer Model ZEUS 9.9 (K053556)

Device Description: The EasyBody 202, EasyBody 203 and EasyBody 205 are non-invasive body composition analyzers intended for use only in healthy subjects between the age of 5-89. The devices employ BIA(Bio-electrical Impedance Analysis) method, 4 electrodes for EasyBody 202 and EasyBody 203, 8 electrodes for EasyBody 205, and then measure body composition using an experimentally derived algorithm. The devices are powered by four AA batteries (DC 6V) or AC adapter.

Intended use: Body Composition Analyzer Models EasyBody 202 and EasyBody 203 are intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat),

LBM(Lean Body Mass), BMR(Basic Metabolic Rate), recommended daily calorie intake, daily exercise time, and sort and term of exercise using the BIA(Bio-electrical Impedance Analysis) method.

Body Composition Analyzer Model EasyBody 205 is intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), BMR(Basic Metabolic Rate), Segmental LBM, recommended daily calorie intake. daily exercise time, and sort and term of exercise using the BIA(Bio-electrical Impedance Analysis) method.

The EasyBody 202, EasyBody 203 and EasyBody 205 measure the impedance and weight of the user, and are intended for use only in healthy subjects between the age of 5-89.

Technologic characteristics: The devices EasyBody 202, EasyBody 203 and EasyBody 205 have been compared to the predicate device ZEUS 9.9 such as a comparing table of technology characteristics. The differences in this submission don't raise new questions concerning either safety or effectiveness.

Non-clinical and clinical tests: The subject devices EasyBody 202, EasyBody 203 and EasyBody 205 meet the requirements of IEC 60601-1, EN 60601-1-2 and ISO 10993 series. The results of clinical comparison tests with predicate device ZEUS 9.9 demonstrate that there is no significant difference between the subjected devises and the predicate device.

Conclusions: Based on non-clinical and clinical tests, the subject devices EasyBody 202, EasyBody 203 and EasyBody 205 are as safe, as effective, and perform as well as the predicate device ZEUS 9.9. Accordingly, the subject devices are substantially equivalent to the predicate device.

< Comparison Table of technical characteristics >

Items	Zeus 9.9	EasyBody 202	EasyBody 203	EasyBody 205
510(k) #	K053556	New	New	New
Intended Use	Body composition Analyzer	Same	Same	Same
Indications for use	Estimated of: 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 Actual : Impedance, BMI(Body Mass Index), weight, WHR(Waist to Hip Ratio) Healthy subjects of the age of 7-89	Estimated of: PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), BMR(Basic Metabolic Rate), recommended daily calorie intake, daily exercise time, sort and term of exercise Actual: Impedance, weight Healthy subjects of the age of 5-89	Estimated of: PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), BMR(Basic Metabolic Rate), recommended daily calorie intake, daily exercise time, sort and term of exercise Actual: Impedance, weight Healthy subjects of the age of 5-89	Estimated of: PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), BMR(Basic Metabolic Rate), Segmental LBM, recommended daily calorie intake, daily exercise time, sort and term of exercise Actual: Impedance, weight Healthy subjects of the age of 5-89
Analysis Method	Bio-electrical Impedance Analysis (BIA)	Same	Same	Same
Operating parameters	Frequency: 1,5,50, 250,550,1000kHz	Frequency: 50kHz	Frequency: 50kHz	Frequency: 50kHz
Electrode type	Tactile	Same	Same	Same
Number/ Placement of Electrodes	8 electrodes Placed on Hands and feet(or ankle) (Tetra-polar Electrode method)	4 electrodes Placed on feet (Tetra-polar Electrode method)	4 electrodes Placed on feet (Tetra-polar Electrode method)	8 electrodes Placed on Hands and feet (Tetra-polar Electrode method)

Items	Zeus 9.9	EasyBody 202	EasyBody 203	EasyBody 205
Patient Position	Upright	Same	Same	Same
Impedance Measuring Site	Whole body, Right Arm, Right Leg, Left Arm, Left Leg Trunk	Foot to Foot	Foot to Foot	Whole body, Right Arm, Right Leg, Left Arm, Left Leg, Trunk
Impedance Measurement Range	100 ~ 950 ohms	Same	Same	Same
Measuring height	110 ~ 200 cm	100 ~ 200 cm	100 ~ 200 cm	100 ~ 200 cm
Measuring weight	10 ~ 250 kg	1~150 kg	1~150 kg	1~150 kg
Measuring PBF	3 ~ 50%	Same	Same	Same
Measuring Time	Within 1 minute	About 15sec	About 15sec	About 15sec
Electrical current applied during measurement	Maximum current 360uA	Maximum current 180uA	Maximum current 180uA	Maximum current 180uA
Power consumption	50VA	0.36VA	0.36VA	0.36VA
Power Supply	AC120V 50/60Hz	AA Battery DC6V or AC Adapter	AA Battery DC6V or AC Adapter	AA Battery DC6V or AC Adapter
Operating ambient	Temp: 10 ~ 40℃ RH: 30 ~ 75%	Same	Same	Same
Storage ambient	Temp: -20 ~ 60℃ RH: lower than 95%	Same	Same	Same
Dimensions (W x L x H)	470 x 655 x 1220mm	310 x 311 x 38.5mm	300 x 356 x 79mm	300 x 300 x 369mm
Weight	45Kg	1.7kg	2.2kg	2.7kg

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2007

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REPUBLIC OF KOREA

Re: K072325
Trade/Device Name: JAWON MEDICAL BODY COMPOSITION ANALYZER MODELS EasyBody 202, EasyBody 203, and EasyBody 205
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: November 19, 2007
Received: November 21, 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 (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

Section 4

Indications for Use

510(k) Number (if known): K072325

Device Name: JAWON MEDICAL BODY COMPOSITION ANALYZER
MODELS EasyBody 202, EasyBody 203 and EasyBody 205

Indications For Use:

The EasyBody 202 and EasyBody 203 are intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), BMR(Basic Metabolic Rate), recommended daily calorie intake, daily exercise time, and sort and term of exercise using the BIA(Bio-electrical Impedance Analysis) method.

The EasyBody 205 is intended to estimate PBF(Percentage of Body Fat), MBF(Mass of Body Fat), LBM(Lean Body Mass), BMR(Basic Metabolic Rate), Segmental LBM, recommended daily calorie intake, daily exercise time, and sort and term of exercise using the BIA(Bio-electrical Impedance Analysis) method.

The EasyBody 202, EasyBody 203 and EasyBody 205 measure the impedance and weight of the user, and are intended for use only in healthy subjects between the age of 5-89.

Prescription Use_____ AND/OR Over-The-Counter Use X

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IN NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072325