JAWON

MEDICAL

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510(k) Summary

BODY COMPOSTION ANALYZER
Models VENUS 9.9 and ZEUS 5.5

AUG 3 1 2006

1. COMPANY INFORMATION.

Name : Jawon Medical CO., LTD.

Address : 1208-12, Sinsang-Li, Jinryang-Eup, Kyungsan-City, Kyungsang-Bukdo, Korea.

Phone : 82-53-856-0993

Contact : Mr. J.H. CHO , Senior Engineer, R&D center

2. DEVICE IDENTIFICATION.

Trade Name : Model ZEUS 9.9/VENUS 5.5 BODY COMPOSITION ANALYZER

Common name and Classification name : BODY COMPOSITION ANALYZER , Impedance plethysmograph, MNW

3. PREDICATE DEVICE.

BODYSTAT Quad scan 4000 Body Composition Analyzer, K002835, decision on 07/03/2001

TANITA Body Composition Analyzer BC-418, K033157, decision on 08/08/2004

4. DEVICE DESCRIPTION.

General: Model ZEUS 9.9/VENUS 5.5 of Jawon Medical is compact, automatic Impedance plethysmographer intended for estimating of body composition of user such as 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 age of 7-89. The only difference between the ZEUS 9.9 and VENUS 5.5 is head part of main unit; that is, the head part of the ZEUS 9.9 has a key pad and touch screen while the head part of the VENUS 5.5 has only a touch screen.

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Operation: The subject device employs a measurement algorithms which is called BIA method, to measure user's body composition.
ZEUS 9.9/VENUS 5.5 device's tetra-polar type electrode connect to human body and then send an minute electric current like 360 μA human body and then ZEUS 9.9/VENUS 5.5 device can measure impedance of the human body.
ZEUS 9.9/VENUS 5.5 can measure body composition of user with personal data which already saved height, weight, gender, ages and new calculated body impedance.

Power: Model ZEUS 9.9/VENUS 5.5 is AC line powered(AC 110~120V, 50/60Hz)

5. **INTENDED USES:** The ZEUS 9.9 and VENUS 5.5 body composition analyzers 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.
The only difference between the ZEUS 9.9 and VENUS 5.5 is head part of main unit; that is, the head part of the ZEUS 9.9 has a key pad and touch screen while the head part of the VENUS 5.5 has only a touch screen.

6. **COMPARISON WITH PREDICATE DEVICE.**
Models ZEUS 9.9/VENUS 5.5 of Jawon devices have been compared with BODYSTAT Quad Scan 4000 of BODYSTAT LTD and TANITA Body Composition Analyzer BC-418. The intended uses of Jawon devices and predicate devices are the same. Both of Jawon devices and predicate devices use BIA(Bio-electrical Impedance Analysis) method to estimate body composition parameters.
The differences between Jawon devices and predicate devices are as follows;
Measurement frequency is 50, 5, 100, 200kHz for BODYSTAT Quad Scan 4000, and 50kHz for Tanita BC-418 instead of 50, 1, 5, 250, 550,1000kHz for Jawon devices.
4 electrodes are placed on hands and feet for BODYSTAT Quad Scan 4000 and 8 electrodes on hands and feet for Tanita BC-418 instead of 8 electrodes on hands and feet(or ankle) for Jawon devices.
Impedance measurement site is whole body for BODYSTAT Qaud Scan 4000 and right arm, right leg, left arm, left leg and trunk for Tanita BC-418 instead of whole body, right arm, right leg, left arm, left leg and trunk for Jawon devices.
Therefore, there is no difference in intended use and no technologic differences that raise new questions concerning either safety or effectiveness.

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7. Non-clinical tests

The ZEUS 9.9 and VENUS 5.5 body composition analyzers meet of the requirements of international standards IEC 60601-1, IEC 60601-1-2, and ISO 10993 series.

8. Clinical tests

Comparison testing was performed using the ZEUS 9.9 body composition analyzer and predicated devices-BODYSTAT Quad Scan 4000 and TANITA BC-418 in healthy subjects between the age of 7-89. Results of the testing showed that the ZEUS 9.9 body composition analyzer is equivalent in performance to the predicate devices-BODYSTAT Quad Scan 4000 and TANITA BC-418. There is no significant difference between the ZEUS 9.9 body composition analyzer and predicate devices-BODYSTAT Quad Scan 4000 and TANITA BC-418.

9. Conclusions

Based on the indications for use, clinical data, non-clinical testing, and comparison to predicate devices, the ZEUS 9.9 and VENUS 5.5 body composition analyzers are as safe, as effective, and perform as well or better than the predicate devices-BODYSTAT Quad Scan 4000 Body Composition Analyzer and TANITA Body Composition Analyzer BC-418. Accordingly,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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c/o Mr. Heung Bong Lim
MI Consulting Co., Ltd.
Room 624, Life Officetel, 61-3
Yoido-Dong, Youngdeungpo-GU
Seoul, Korea
REPUBLIC OF KOREA 150-731

AUG 31 2006

Re: K053556
Trade/Device Name: JAWON MEDICAL BODY COMPOSITION ANALYZER, MODELS ZEUS 9.9 AND VENUS 5.5
Regulation Number: 21 CFR §870.2772
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: August 2, 2006
Received: August 2, 2006

Dear Mr. Lim:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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): K053556

Device Name: JAWON MEDICAL BODY COMPOSITION ANALYZER
MODELS ZEUS 9.9 AND VENUS 5.5

Indications For Use:

The ZEUS 9.9 and VENUS 5.5 body composition analyzers 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.

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The only difference between the ZEUS 9.9 and VENUS 5.5 is head part of main unit; that is, the head part of the ZEUS 9.9 has a key pad and touch screen while the head part of the VENUS 5.5 has only a touch screen.

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 K053556