DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 18, 2015

Jawon Medical Co., Ltd.
Won Hee Park
President
1208-12, Sinsang-ri, Jinryang-eup
Kyungsan-city
Kyungsang-Bukdo 712-830
Republic of Korea

Re: K140045
Trade/Device Name: Jawon Body Composition Analyzers, Model X-CONTACT 350; X-CONTACT 350M; X-CONTACT 350S
Regulation Number: 21 CFR 870.2770
Regulation Name: Analyzer, body composition
Regulatory Class: II
Product Code: MNW
Dated: November 7, 2014
Received: November 20, 2014

Dear Won Hee Park,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): **K140045**

Device Name: **Jawon Body Composition Analyzers Model X-CONTACT 350; X-CONTACT 350M; X-CONTACT 350S**

Indications For Use:

These devices calculates and estimates body composition parameters by using measured weight and impedance and entered height, age and gender. It shows body composition of Weight, Standard weight, Lean Body Mass, Total Body Water, Intra Cellular Water, Extra Cellular Water, B.M.I. (Body Mass Index), Mass of Body Fat, Percent of Body Fat, Basal Metabolic Rate, Impedance, Body Type, Target to Control, Goal setter.

In case of whole body, it shows more items including Waist to Hip Ratio, Ratio of E.C.W. /T.B.W., Segmental analysis (lean body mass of arms, legs, and trunk).

These devices can only estimate the body composition parameters with the exception of Weight, BMI, and impedance. These devices are only for use with generally healthy individuals of a specified age range.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Doc. No. 4
510(K) Summary [K140045]

[As required by 21 CFR 807.92]

Date Prepared: 02/18/15

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Contact: MEDMONTS Co. Ltd. (W.S. Park)
Life-officetel 320, 40 63 ro, Youngdeungpo-gu, Seoul 150-731,

Trade Name: Body Composition Analyzer
Model X-Contact 350, X-Contact 350M, X-Contact 350S

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 ioi 353{K092431) and EasyBody 202(K072325)

A list of 510(k) Devices To Be Cleared: X-Contact 350, X-Contact 350M, X-Contact 350S

| No. | Model Name | Indication for Use |
|---|---|---|
| 1 | X-Contact 350 | Whole Body Composition Analyzer<br><br>These devices calculates and estimates body composition parameters by using measured weight and impedance and entered height, age and gender. It shows body composition of Weight, Standard weight, Lean Body Mass, Total Body Water, Intra Cellular Water, Extra Cellular Water, B.M.I. (Body Mass Index), Mass of Body Fat, Percent of Body Fat, Basal Metabolic Rate, Impedance, Body Type, Target to Control, Goal setter.<br><br>In case of whole body, it shows more items including Waist to Hip Ratio, Ratio of E.C.W. /T.B.W., Segmental analysis (lean body mass of arms, legs, and trunk).<br><br>These devices can only estimate the body composition parameters with the exception of Weight, BMI, and impedance. These devices are only for use with generally healthy individuals of a specified age range. |
| 2 | X-Contact 350M | Upper Body Composition Analyzer<br><br>These devices calculates and estimates body composition parameters by using |

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|---|---|---|
| | | measured weight and impedance and entered height, age and gender. It shows body composition of Weight, Standard weight, Lean Body Mass, Total Body Water, Intra Cellular Water, Extra Cellular Water, B.M.I. (Body Mass Index), Mass of Body Fat, Percent of Body Fat, Basal Metabolic Rate, Impedance, Body Type, Target to Control, Goal setter.<br><br>In case of whole body, it shows more items including Waist to Hip Ratio, Ratio of E.C.W. /T.B.W., Segmental analysis (lean body mass of arms, legs, and trunk).<br><br>These devices can only estimate the body composition parameters with the exception of Weight, BMI, and impedance. These devices are only for use with generally healthy individuals of a specified age range. |
| 3 | X-Contact 350S | Lower Body Composition Analyzer<br><br>These devices calculates and estimates body composition parameters by using measured weight and impedance and entered height, age and gender. It shows body composition of Weight, Standard weight, Lean Body Mass, Total Body Water, Intra Cellular Water, Extra Cellular Water, B.M.I. (Body Mass Index), Mass of Body Fat, Percent of Body Fat, Basal Metabolic Rate, Impedance, Body Type, Target to Control, Goal setter.<br><br>In case of whole body, it shows more items including Waist to Hip Ratio, Ratio of E.C.W. /T.B.W., Segmental analysis (lean body mass of arms, legs, and trunk).<br><br>These devices can only estimate the body composition parameters with the exception of Weight, BMI, and impedance. These devices are only for use with generally healthy individuals of a specified age range. |

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| Technologic Characteristics | These subject devices X-CONTACT 350, X-CONTACT 350M, X-CONTACT 350S have same intended use and technology characteristics as predicate devices. See enclosed document number 9 (Substantial Equivalence Discussion).The differences in this submission do not raise new questions concerning either their safety or effectiveness. |
| Non-Clinical and Clinical Tests | These subject devices X-CONTACT 350, X-CONTACT 350M, and X-CONTACT 350S meets the requirements of IEC 60601-1, IEC 60601-1-2 and in-house test criteria. The results of performance tests using X-Contact 350 demonstrated that there is no significant difference in measurements. See the enclosed document number 15 (Performance Test-Clinical) |
| Conclusion: | Based on non-clinical and clinical tests, the modified devices X-CONTACT 350, X-CONTACT 350M, and X-CONTACT 350S, are as safe, as effective, and perform as predicate devices perform. (See document number 9-Substantial Equivalents Discussion). Accordingly the subject devices X-CONTACT 350, X-CONTACT 350M, and X-CONTACT 350S, are substantially equivalent to the predicate devices. |