Withings

Section 5 - 510(k) Summary

SEP 27 2012

Date of Summary Preparation: 06/28/2012

1. Submitter's Identifications

Submitter's Name: ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD.
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2. Correspondent's Identifications

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3. Name of the Device

Device Classification Name: Analyzer, Body Composition (Impedance Plethysmograph)
Product Name: Smart Body Scale
Trade Name: Withings
Model: WBS01
Classification Panel: Cardiovascular
Common/Usual Name: Body Composition Analyzer/Scales
Product Code: MNW
Device Classification: Class II
Contraindications: Do not use the Body Scale if you have a pacemaker or other internal medical device.

4. The Predicate Devices

TRANSTEK, Glass Body Analyzer, Model GBF-830, K102191

5. Device Description

5.1 Technology of the device:

Bioelectrical Impedance:

WBS01 Smart Body Scale uses the BIA (Bioelectrical Impedance Analysis) technique. This method measures body composition by sending a low, safe electrical current through the body.

The current passes freely through the fluids contained in muscle tissue, but encounters difficulty/resistance when it passes through fat tissue. This resistance of the fat tissue to the current is termed 'bioelectrical impedance', and is accurately measured by WBS01 Smart Body Scale.

Wireless Connectivity:

WBS01 Smart Body Scale embeds a 802.11 (Wi-Fi) module that allows it to connect to the Internet. This module is a product add-on that is entirely independent from the body analyzer function, which does not rely on the wireless connection to carry out a bioelectrical impedance analysis and display its results. The scale uses this connectivity to offer users a complementary web and mobile interface to the scale's display, although users are instructed in the provided user manual that the only reference values are the measures displayed on the scale's display. By design, the body analysis and Wi-Fi functions never are enabled at the same time. The scale only connects to the Internet while no weight or bioelectrical impedance measures are being performed, and if a person steps on the scale while the Wi-Fi module is active, Wi-Fi immediately gets turned off therefore allowing the display and body analysis function to be enabled. The users profile details are stored locally in the scale so that they are immediately available when a bioelectrical impedance analysis needs to be performed. The scale without its Wi-Fi module is therefore an autonomous body fat analyzer, Wi-Fi functionality being a product add-on not being part of the body analyzer function and not affecting the safety and effectiveness of the body analyzer function in any way.

5.2 Device functions

A, Measuring weight, BMI and body fat:

Step on the scale and the scale will display your weight, BMI and body fat.
Unit Switch function: Change the weight unit among KG/LB/ST LB

B, Automatic recognition function:

The scale can automatically recognize you based on your weight reading. Later on, the scale keeps in memory your last weight reading to recognize you. The scale can however only determine your correct identity if no other user weighs within 6.6 pound range, otherwise the scale can only narrow down the choices and displays the various identity options on screen. The appropriate identity is selected by bending left or right.

C, Warning messages Function:

Lo = Low battery warning: Replace the batteries, always replace all batteries at the same time.

D, Wi-Fi Connectivity:

Easily create your profile in Withings' web application and the scale will automatically retrieve it thanks to its Wi-Fi connectivity. You must enter your height, date of birth, gender and activity level (athlete/ non-athlete) while creating your profile. Benefit from a complementary interface to view the history of your weight and body fat readings.

Key function: profile definition, complementary interface.

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6. Intended Use of Device

The Withings WBS01 Smart Body Scale is a body analyzer that measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.

It is not intended for being used by pregnant women or children under the age of 18.

7. Summary of Substantial Equivalence

7.1 Difference between proposed device and the predicate device

Table: The comparison of Withings WBS01 Smart Body Scale and the predicate device, TRANSTEK Glass Body Analyzer (Model: GBF-830)

Feature	Proposed Device: Withings WBS01 Smart Body Scale	Predicate Device: TRANSTEK Glass Body Analyzer Model: GBF-830
Manufacturer	ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD	ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD
Classification	21 CFR 870.2770	21 CFR 870.2770
Product Code	MNW	MNW
Indication for use	The Withings WBS01 Smart Body Scale measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.	The Transtek Glass Body Analyzer measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, bone mass, and muscle mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.
Device description	Withings WBS01 Smart Body Scale utilizes a "foot-to-foot" bioelectrical impedance analysis (BIA) technology to determine internal body composition.	TRANSTEK Glass Body Analyzer utilizes a "foot-to-foot" bioelectrical impedance analysis (BIA) technology to determine internal body composition.
Analysis method	BIA (Bioelectrical Impedance Analysis)	BIA (Bioelectrical Impedance Analysis)
Operating parameters	50 KHz	50 KHz
Number of electrodes	4	4
Power source	4*AAA	4*AAA
Operating keys	No operating key, 1 unit switch, 1 pairing button	4
IP Connectivity	802.11b/g (Wi-Fi)	No IP connectivity

The differences between the two devices are WBS01, 1) disable these measure functions, total body water percentage, bone mass, and muscle mass; 2) add-on a Wi-Fi (IEEE 802.11 b/g) data communication, what user option, which can transmit measurement results to PC or cellular.

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7.2 Discussion

The Withings WBS01 Smart Body Scale has an indication for use and BIA technology similar to the predicate device. The only technological difference between Withings WBS01 Smart body Scale and the predicate device is that the WBS01 embeds a 802.11 b/g (Wi-Fi) module. It is an add-on function that is entirely independent from the body analyzer function, which does not rely on the wireless connection to carry out a bioelectrical impedance analysis and display its results.

The scale uses this connectivity to offer users a complementary web and mobile interface to the scale's display, although users are instructed in the provided user manual that the only reference values are the measures displayed on the scale's display.

By design, the body analysis and Wi-Fi functions never are enabled at the same time. The scale only connects to the Internet while no weight or bioelectrical impedance measures are being performed, and if a person steps on the scale while the Wi-Fi module is active, Wi-Fi immediately gets turned off therefore allowing the display and body analysis function to be enabled.

The users profile details are stored locally in the scale so that they are immediately available when a bioelectrical impedance analysis needs to be performed. The scale without its Wi-Fi module is therefore an autonomous body fat analyzer, Wi-Fi functionality being a product add-on not being part of the body analyzer function and therefore not impacting the safety and effectiveness of the body analyzer function.

Design control activities for the modification were performed and bench tests have been done to ensure that user electrical safety and wireless radiation emission is acceptable in use environment. Particular attention has been paid to those concerns and issues highlighted in the "*Radio-Frequency Wireless Technology in Medical Devices Draft Guidance*" FDA January 3, 2007.
Wi-Fi technology is widely used and proved to be safe and reliable. The use of the industry standard IEEE 802.11 b/g provides a high degree of confidence to the users that the coexistence of Withings WBS01 Smart Body Scale within a domestic/home environment is predictable, easily operation, and provides a high degree of assurance that there is a low risk that intentional electromagnetic radiation from the device will result in unacceptable interference with other electrical equipment in the immediate vicinity.
There is an acceptable, low risk that the radio frequency emissions will result in thermal injury to a patient or user. This is based on our FCC ID certification.

Therefore, the device does not create new significant risk.

As a result, the technological difference of the device does not impact its safety and effectiveness vs. the predicate device.

8. Conclusions

The Withings WBS01 Smart Body Scale is substantially equivalent to the predicate device by having the similar indication for use, same BIA technologies and a technological difference that does not impact the safety or effectiveness of the device.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CHINA

SEP 27 2012

Re: K121971
Trade/Device Name: Withings Smart Body Scale
Model: WBS01
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: August 30, 2012
Received: August 30, 2012

Dear Mr. Wang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

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

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Section 4 - Indications for Use

510(k) Number (if known): K121971

Device Name:

Withings Smart Body Scale
Model: WBS01

Indications for Use:

The Withings WBS01 Smart Body Scale is a body analyzer that measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121971