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510(k) Summary of Safety and Effectiveness

JUN 0 2 2014

Manufacturer and Submitter

Company Name: Fitbit, Inc.
Company Address: 150 Spear Street, Suite 200
San Francisco, CA 94015
Tel 1.650.333.4001
Contact Person: Arndt Hufenbach
Date Summary Prepared: December 2013

Device Name and Classification

Trade/Device Name: ARIA WiFi Smart Scale
Common/Usual Name: Analyzer, Body Composition
Classification Name: Impedance Plethysmograph
Regulation Number: 21 CFR §870.2770
Product Code: MNW
Classification Panel: Cardiovascular Devices
Classification: Class II

Substantial Equivalence

This 510(k) submission demonstrates that the ARIA WiFi Smart Scale is substantially equivalent to the Smart Body Scale (Withings, K121971) in both technology and intended use.

Feature	ARIA WiFi Smart Scale New Device	Withings Smart Body Scale (Predicate) K121971
Classification	21 CFR 870.2770	21 CFR 870.2770
Product Code	MNW	MNW
Indication for Use	The ARIA WiFi Smart Scale is a body analyzer that measures body weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat percentage in generally healthy individuals 10 years of age or older. It is intended for home use only.	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.
Device Description	Fitbit ARIA WiFi Smart Scale uses a "foot-to-foot" bioelectrical impedance analysis (BIA) technology to determine internal body composition	Withings WBS01 Smart Body Scale 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

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Feature	ARIA WiFi Smart Scale New Device	Withings Smart Body Scale (Predicate) K121971
Number of electrodes	4	4
Power Source	4-AA	4-AAA
Operating Keys	None	No operating key, 1 unit switch, 1 pairing button
IP Connectivity	802.11b (WiFi)	802.11b/g (WiFi)
Parameters Measured	Body weight, Body fat composition	Body weight, Body fat composition

Device Description

ARIA is a body weight scale and a body fat analyzer that operates by using a low, safe, battery-generated electrical current through the body (using a bioelectrical impedance analysis technique) to provide body fat and body weight information. After the user registers their scale, the scale automatically recognizes the subject based on body weight and body fat readings. ARIA contains a WiFi module (802.11 module) that allows it to connect to the Internet in the user's home. The module provides a complementary interface to the Fitbit website. Body weight and body fat measurements are independent of internet communication after initial product registration.

The ARIA scale automatically measures body weight and body fat composition. The scale recognizes the user based on previous weight readings, and can accept up to eight (8) different users. The 16 most recent readings are kept in memory on the scale and readings are also transmitted to the user's optional fitbit.com personal account for trending. If users have similar weight, the proper identity can be selected by tapping the scale.

Intended Use/Indications for Use

The ARIA WiFi Smart Scale is a body analyzer that measures body weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat percentage in generally healthy individuals 10 years of age or older. It is intended for home use only.

Performance - Bench Testing

The ARIA WiFi Smart Scale has been tested according to IEC 60601-1, IEC 60601-1-2 and was found to meet all requirements. Performance data (reliability testing and human factors testing) also support that the ARIA device meet its specified criteria.

Performance – Clinical Performance Testing

A small comparative clinical study was conducted to compare body fat composition (%) in 25 male and 25 female subjects using the ARIA WiFi Smart Scale vs. the predicate device. This study was conducted in generally healthy subjects (without acute or chronic illness, disease, or condition such as pregnancy). Results of this study lead to the conclusion that the measurements from ARIA were not statistically different from the predicate device ($p>0.05$) and body fat measurements varied by <8% from one another.

Date of summary: April 2, 2014

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 2, 2014

Fitbit, Inc.
% Diane Horwitz, Ph.D.
Regulatory Affairs Consultant
Mandell Horwitz Consultants, LLC
2995 Steven Martini Drive
Fairfax, VA 22031

Re: K133872
Trade/Device Name: ARIA WiFi Smart Scale
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: April 4, 2014
Received: April 4, 2014

Dear Diane Horwitz,

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

Indications for Use

510(k) Number (if known): K133872

Device Name: ARIA WiFi Smart Scale

Indications For Use:

The ARIA WiFi Smart Scale is a body analyzer that measures body weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat percentage in generally healthy individuals 10 years of age or older. It is intended for home use only.

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

Benjamin R. Fisher -S
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