TRANSTEK

Section 6 - 510(k) Summary

Date of Summary Preparation: 05/08/2013

SEP 18 2013

1. Submitter's Identifications

Submitter's Name: Guangdong Transtek Medical Electronics Co., Ltd
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2. Correspondent's Identifications

Correspondent's Name: A03 Lab of BTS
Address: No.1 Fanghua Street, Hi-tech Zone, Chengdu 610041, Sichuan, China
Contact Person: Leo Wang
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3. Name of the Device

Device Classification Name: Analyzer, Body Composition (Impedance Plethysmograph)
Product Name: Glass Body Fat Analyzer
Trade Name: TRANSTEK
Models: LS203-B
Classification Panel: Cardiovascular
Common/Usual Name: Body Composition Analyzer/Scales
Product Code: MNW
Regulation No.: 870.2770
Device Classification: Class II

4. The Predicate Devices

TRANSTEK, Glass Body Analyzer, Model LS206-E, K123781

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5. Device Description

Transtek Glass Body Fat Analyzer uses BIA (Bioelectrical Impedance Analysis) technology which passes an electrical current through the body to estimate body fat mass, total body water, muscle mass and bone mass. The electrical current is low and may not be felt. 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 Glass Body Fat Analyzer LS203-B.

This method simultaneously calculates your personal weight, body fat, total body water, muscle mass and bone mass, giving you a more accurate reading of your overall health and fitness.

Transtek Glass Body Fat Analyzer GLS203-B embeds a Bluetooth module that allows it to connect to nearby BT receiving terminal. Once measurement is over, the LCD of device displays measurement results, and the device will start to send out measurement data to paired BT terminal at the same time. Thus users can receive, display, and storage measurement results from LS203-B unit through mobile BT terminal.

6. Intended Use of Device

The TRANSTEK Glass Body Fat Analyzer measure weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, muscle mass, and bone mass in generally healthy adults 18 years of age or older.

It is intended for use in the home/domestic setting only.

7. Design Control Activities and Performance Tests Summary

Design control activities for this modification were performed and bench tests have been done. Those performance tests, risk management, and design verification tests provide demonstration that the difference does not raise any new questions of safety and effectiveness.

LS203-B conforms to the following standards:

ISO14971, Risk management to medical devices

IEC60601-1, Electrical safety; IEC60601-1-2, Electromagnetic compatibility

FCC Part 15, EMI tests of FCC Radiation rules and regulations

Explanation: The wireless function does not affect body analyzer measurement function. Therefore we have not done the Clinical test.

8. Summary of Substantial Equivalence

8.1 Difference between proposed devices and the predicate device

The only significant difference between the two devices is that modified device uses Bluetooth instead of RF which the original device used.

More modification details are described in this submission.

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8.2 Discussion

Transtek Glass Body Fat Analyzer LS203-B has identical indication for use, fundamental scientific technology, dimensional specifications, and similar performance specifications, software/firmware, functions, labeling to the predicate device.

The only significant difference between LS203-B and the predicate device is that the modified device's wireless data transmission function achieved by a BT module instead of original's RF module. The Bluetooth does not raise any new questions of safety and effectiveness.

All required design control activities have been implemented and all applicable performance tests have been done according with demands of FDA regulations. We found that the modified device does not create new significant risk.

9. Conclusions

Transtek Glass Body Fat Analyzer LS203-B is substantially equivalent to the predicate device LS206-E by having identical indication for use, identical fundamental scientific technologies, and similar wireless data communications that does not impact the safety and effectiveness of the device.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 18, 2013

Guangdong Transtek Medical Electronics Co., Ltd
Leo Wang
No.1 Fanghua Street, Hi-tech District
Chengdu, Sichuan, 610041 CH

Re: K131394
Trade/Device Name: Transtek Glass Body Fat Analyzer Model LS203-B
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph (Body Composition Analyzer/Scales)
Regulatory Class: Class II
Product Code: MNW
Dated: Undated
Received: August 19, 2013

Dear Leo 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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bram D Zuckerman -S

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 5 - Indications for Use

510(k) Number (if known): K131394

Device Name:

Transtek Glass Body Fat Analyzer
Model: LS203-B

Indications for Use:

The Transtek Glass Body Fat Analyzer measure 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.

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)

Bram D. Zuckerman -S
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