510(K) SUMMARY

OCT - 7 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92, and the relevant 510(k) submission guidance on September 23, 2011.

The assigned 510(k) number is: K111404

1. Submitter's Identifications:
   Contact Person : Mr. Kevin Deng
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2. Name of the Device & Classification Information:
   Trade Name(Proprietary Name) : Huibao Body Fat Scale, model BF-136
   Common Name(Usual Name) : Huibao Body Fat Scale, model BF-136.
   Classification Name : Impedance Plethysmograph
   Classification Number (Code) : 21 CFR/Part 870.2770(MNW)

3. Information of the 510(k) Cleared Device (Predicate Device):
   TANITA InnerScan Body Composition Monitor model BC-534(K040778)

4. Device Description:
   The Huibao BF-136 Body Fat Scale is a program-controlled body composition analyzer that utilizes Foot-to-Foot BIA(bioelectrical impedance analysis) to determine body weight, total body fat percentage, total body water percentage, bone mass, and daily calorie intake(DCI) for the person whose age is between 10 and 80 years old.

   The Huibao BE-136 Body Fat Scale measures body weight and impedance for the person standing on four foot electrodes which generate a 100 μA/30KHz current for the measurement of body impedance, and then estimates and displays the information of body weight, total body fat percentage, total body water percentage, bone mass, and daily calorie intake(DCI) via taking the input personnel body condition parameters into account.

5. Intended Use:
   The Huibao BE-136 Body Fat Scale measures body weight and impedance for the person standing on the four electrodes, and then estimates and displays the information of body weight, total body fat percentage,total body water percentage, bone mass, and daily calorie intake(DCI) using Foot-to-Foot BIA(bioelectrical impedance analysis) method. BF-136 is intended for the healthy person whose age is between 10 and 80 years old

6. Comparison to the 510(k) Cleared Device (Predicate Device):
   Comparison for the scientific concepts and significant performance characteristics : As the following comparison table :

Scientific Concepts and significant Performance Characteristics:

	Tanita InnerScan Body composition Monitor Models BC-534, K040778	Huibao Body Fat scale, Model: BF-136
INTENDED USE:	A combination non-invasive device, which determines weight and estimates total body fat percentage, total body water percentage, bone mass, and daily calorie intake with the use of BIA (Bioelectrical impedance analysis).	A combination non-invasive device, which determines weight and estimates total body fat percentage, total body water percentage, bone mass, and daily calorie intake with the use of BIA (Bioelectrical impedance analysis).
PRODUCT DESCRIPTION:	Body composition monitor / scale that utilizes a "foot-to-foot" BIA (bioelectrical impedance) technology to determine internal body composition.	Body composition monitor / scale that utilizes a "foot-to-foot" BIA (bioelectrical impedance) technology to determine internal body composition.
ANALYTICAL METHOD/	Foot-to-Foot BIA.	Foot-to-Foot BIA.
Impedance Measurement Circuit	180 μA/50KHz impedance measuring current through four foot electrodes.	100 μA/30KHz impedance measuring current through four foot electrodes.

7. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence:
Compliance is ensure via the following voluntary standard testing reports:
1> EN/IEC 60601-1 for electrical safety compliance tested by accredited laboratory
2> EN/IEC 60601-1-2 for EMC compliance tested by accredited laboratory.

8. Summary discussion of the clinical tests performed for determination of Substantial Equivalence:
Performance clinical test for the comparison of total body fat percentage, total body water percentage, bone mass, and daily calorie intake(DCI) was performed by manufacturer. For the clinical test, 35 male and female subjects whose age are between 10 and 80 years old were chosen as the investigated users to take comparison measurement. For the comparison, it is considered acceptable that the deviation between our device Huibao/BF-136 and the predicate device TANITA/BC-534(K040778) is within 10%. Consequently, the maximum and minimum deviation of comparison testing and results are as the following table:

Comparison feature	Max. deviation	Min. deviation	Verdict
1. Body Fat Percentage	9.09 %	-8.70 %	Acceptable
2. Water Percentage	8.83 %	-3.33 %	Acceptable
3. Bone Mass	9.09 %	-5.88 %	Acceptable
4. Daily calorie intake	1.18 %	-1.45 %	Acceptable

During the execution of the clinical test, no any adverse effect or complication was encountered for every individual who was subjected to the clinical test.

9. Conclusions

Based on the clinical test comparison results for the measurement performance of total body fat percentage, total body water percentage, bone mass, and daily calorie intake(DCI) performed by manufacturer as presented in section 8, and the completed electrical safety and EMC testing report performed by accredited laboratory presented in section 7, it was concluded that the Huibao Body Fat Scale, model BF-136 as well as the predicate device, the TANITA InnerScan Body Composition Monitor model BC-534(K040778), had been proven to meet the relevant safety and efficacy requirements of the device, and therefore is considered as Substantial Equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OCT 7 11

Mr. Kevin Deng
Official Correspondent
Zhongshan Huibao Weighing Apparatus Co., Ltd.
Chang An Road
GUZHEN TOWN ZHONGSHAN CITY GUANGDONG 528421
CHINA

Re: K111404
Trade/Device Name: Huibao Body Fat Scale, model BF-136
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: September 26, 2011
Received: September 28, 2011

Dear Mr. Deng:

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,

Herbert P. Lerner, M.D., Director (Acting)
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): K111404

Device Name: Huibao Body Fat Scale, model BF-136

Indications For Use:

The Huibao BE-136 Body Fat Scale measures body weight and impedance for the person standing on the four foot electrodes, and then estimates and displays the information of body weight, total body fat percentage, total body water percentage, bone mass, and daily calorie intake(DCI) using Foot-to-Foot BIA(bioelectrical impedance analysis) method. BF-136 is intended for the healthy person whose age is between 10 and 80 years old

Prescription Use ____ OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K111404

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