510(k) SUMMARY

submitted in accordance with the requirements of SMDA 1990 and 21 CFR Section 807.92

JUL - 7 2009

Trade Name: TANITA Body Composition Analyzer: Model SC-331
Common Name: Body Composition Analyzer
Classification Name: ANALYZER, BODY COMPOSITION 21 CFR §807.92

Description of Applicant Device:

The TANITA Body Composition Analyzer SC-331 is a computer-operated body composition analyzer that utilizes BIA (bioelectrical impedance analysis) to determine body mass index (BMI), total body fat percent, total body water percent and weight, muscle mass (skeletal and smooth), physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate (BMR), daily caloric intake (DCI), metabolic age, and target body fat percent with predicted weight and fat mass for use by adults and children.

Indications For Use:

The TANITA Body Composition Analyzer is indicated for use in the measurement of weight and impedance, and the estimation of body mass index (BMI), total body fat percent, total body water percent and weight, muscle mass (skeletal and smooth), physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate (BMR), daily caloric intake (DCI), metabolic age, and target body fat percent with predicted weight and fat mass, using BIA (Bioelectrical Impedance Analysis).

The device is indicated for use for healthy children 5-17 years old and healthy adults with active, moderately active, to inactive lifestyles.

Predicate Devices:

TANITA Body Fat Analyzer Professional and Consumer Models K014009 and K040778.

Scientific Concepts and Significant Performance Characteristics:

*Same as shown in SECTION 9, and APPENDIX 1, (Substantial Equivalence Matrix)

	Body Composition Analyzer SC-331 Specification	Body Composition Analyzer TBF-215/300/310/410, BF-350	Body Composition Monitor BC-53X
510(k) number	New	K014009	K040778
Product Description	Body composition analyzer that utilizes a BIA technology to determine internal body composition.	Body composition analyzer that utilizes a BIA technology to determine internal body composition.	Body composition analyzer that utilizes a BIA technology to determine internal body composition.
Analytical Method / Measurement	Patented "Foot-to-Foot" BIA, In house BIA and DEXA reference	Patented "Foot-to-Foot" BIA, In house BIA and DEXA reference	Patented "Foot-to-Foot" BIA, In house BIA and DEXA reference
Measurement Frequency	50kHz	50kHz	50kHz
Number of Electrodes	4	4	4
Specifications			
Weight Capacity	600 lb / 270 kg or 450 kg / 1,000 lb	270 kg / 600 lb	150 kg / 330 lb
Weight Increments	0.2 lb / 100 g or 0.1 lb / 50 g	100 g / 0.2 lb	100 g / 0.2 lb
Body Fat % Increments	0.1%	0.1%	0.1%
User Memory	4	4	4
Input Age	5 - 99	7 - 99	7 - 99
	5-17: Child	7-17: Child	7-17: Child
	18-99: Adult	18-99: Adult	18-99: Adult
Input Height	3' - 7' 11.5" / 90 - 249.9cm	3' - 7' 11.5" / 90 - 249.9cm	3' 4.0" - 7' 3.0" / 100-220cm
Input Activity Level	-	-	1 - 3
Input Body Type	Standard / Athlete	Standard / Athlete	Standard / Athlete
Recall Function	-	-	✓
Power Supply	AC Adapter / DC7V	AC Adapter / DC5V	AA Batteries
Printer Function	✓	✓	-
Computer Interface	RS-232C & USB	RS-232C	-

Indicate for Use						
	Print-Out	**Display**	**Print-Out**	**Display**	**Print-Out**	**Display**
Actual:						
Weight	✓	✓	✓	✓	-	✓
Impedance	✓	-	✓	-	-	-
Estimated:						
FAT %	✓	✓	✓	✓	-	✓
FAT Mass	✓	-	✓	-	-	-
FAT % - Indicator	✓	-	In the manual	-	-	✓
Predicated Fat Mass	✓	-	✓	-	-	-
Predicated Weight	✓	-	✓	-	-	-
FFM	✓	-	✓	-	-	-
Muscle Mass	✓	-	-	-	-	✓
Muscle Mass - Indicator	✓	-	-	-	-	In the manual
Physique Rating	✓	-	-	-	-	✓
Total Body Water	✓	-	✓	-	-	✓
Total Body Water %	✓	-	-	-	-	✓
BMR / DCI	✓	-	✓	-	-	✓
BMR - Indicator	✓	-	-	-	-	In the manual
Metabolic Age	✓	-	-	-	-	✓
Visceral Fat Rating	✓	-	-	-	-	✓
Visceral Fat Level - Indicator	✓	-	-	-	-	✓
Bone Mass	✓	-	-	-	-	✓
BMI	✓	-	✓	-	-	-
BMI - Indicator	✓	-	In the manual	-	-	-

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Side by side comparison of the TANITA Body Composition Analyzer SC-331 to the predicate devices demonstrates that the applicant device are substantially equivalent to those legally marketed devices.

Based on the results of using the previously approved BIA methodology with TANITA's whole body BIA, the TANITA Body Composition Analyzer SC-331 performs equivalently to the predicate devices and therefore is subtantially equivalent.

Toshiniko Ishikawa
TANITA Corporation of America
Product Manager

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Jun 30th, 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2009

Mr. Toshihiko Ishikawa
Product Manager
Tanita Corporation of America, Inc.
2625 South Clearbrook Drive
ARLINGTON HEIGHTS IL 60005

Re: K090479
Trade/Device Name: TANITA Body Composition Analyzer Model SC-331
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Codes: MNW
Dated: June 30, 2009
Received: July 1, 2009

Dear Mr. Ishikawa:

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 090479

Device Name: TANITA Body Composition Analyzer Model SC-331

Indications For Use:

The TANITA Body Composition Analyzer is indicated for use in the measurement of weight and impedance, and the estimation of body mass index (BMI), total body fat percent, total body water percent and weight, muscle mass (skeletal and smooth), physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate (BMR), daily caloric intake (DCI), metabolic age, and target body fat percent with predicted weight and fat mass, using BIA (Bioelectrical Impedance Analysis).

The device is indicated for use for healthy children 5-17 years old and healthy adults with active, moderately active, to inactive lifestyles.

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)

(vers 6/25/05)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090479