APR - 8 2004

SUMMARY

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

Trade Name: **TANITA BC-418, Segmental Body Composition Analyzer**
Common Name: **Body Composition Analyzer / Body Fat Analyzer**
Classification Name: **ANALYZER, BODY COMPOSITION**
21 CFR § 870.2770

Description of Applicant Device:
The TANITA BC-418, Segmental Body Composition Analyzer is a computer-operated body composition analyzer that utilizes BIA (bioelectrical impedance analysis) to determine body fat percent and regional muscle mass.

Intended Uses of Applicant Device:
Intended to be used as a body fat analyzer that determines body weight and estimates body fat and skeletal muscle mass with the use of BIA (bioelectrical impedance analysis). Other outputs include BMR (basal metabolic rate), TBW (total body water), and BMI (body mass index).

Predicate Device:
TANITA Body Fat Analyzer Professional Model TBF-410
K014009

Scientific Concepts and Significant Performance Characteristics:

	Body Fat Analyzer Model TBF-410 K014009	Segmental Body Composition Analyzer Model BC-418
INTENDED USE:	A combination non-invasive device, which determines weight and estimates body fat composition using BIA (bioelectrical impedance analysis).	A combination non-invasive device, which determines weight and estimates body fat composition and muscle mass using BIA (bioelectrical impedance analysis).
PRODUCT DESCRIPTION:	Body composition analyzer/scale that utilizes a "foot-to-foot" BIA (bio- electrical impedance) technology to determine internal body composition.	Body composition analyzer/scale that utilizes segmental BIA (bio-electrical impedance) technology to determine internal body composition.
ANALYTICAL METHOD/MEASUREMENT	▪ Foot-to-Foot BIA ▪ In-house BIA and DEXA reference methods	▪ Segmental BIA ▪ In-house BIA and DEXA reference methods

510(k) SUMMARY, continued

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

Side by side comparisons of the TANITA BC-418, Segmental Body Composition Analyzer to the predicate device Body Fat Analyzer Professional Model TBF-410 clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device.

Based on the results of using the previously approved BIA methodology with our whole body BIA, it was concluded that the TANITA BC-418, Segmental Body Composition Analyzer performs as well as the predicate device and therefore have proven its safety and efficacy.

Rhoda Lynn Valera
TANITA Corporation of America
Regulatory Affairs Specialist

Phone: (847) 434-3966
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September 26, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2004

Ms. Rhoda Lynn N. Valera
Regulatory Affairs Specialist
Tanita Corporation of America, Inc.
2625 South Clearbrook Drive
ARLINGTON HEIGHTS IL 60005

Re: K033157
Trade/Device Name: Tanita Segmental Body Composition Analyzer BC-418
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: January 9, 2004
Received: January 12, 2004

Dear Ms. Valera:

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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K033157

Device Name: TANITA BC-418, Segmental Body Composition Analyzer

Indications for Use: A body composition analyzer that measures body weight and impedance and estimates total and segmental body fat percent, body mass index (BMI), fat mass, fat-free mass, regional muscle mass, basal metabolic rate, and total body water using BIA (bioelectrical impedance analysis) in healthy children (7-17 years old) and healthy adults.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033157