JUN 2 4 2002

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 Body Fat Analyzer TBF/BF/ Ultimate Scale**
Common Name: **Body Fat Analyzer/ Body Fat Monitors/ Body Composition Analyzers/ Body Composition Monitors**
Classification Name: **ANALYZER, BODY COMPOSITION**
21 CFR § 870.2770

Description of Applicant Device:
The TANITA Body Fat Monitor/Scales (multiple models) are designed to determine body weight and body fat composition. Each model will offer a range of features. The system consists of two subdivided stainless steel footpad electrodes mounted on a platform scale. The four-foot electrodes are designed where each foot makes contact with a heel and toe electrode. Impedance of the lower extremities and body weight is measured simultaneously while the subject stands on the scale.

Intended Uses of Applicant Device:
Intended to be used as a body fat analyzer that determines body weight and estimates body fat composition with the use of BIA (bioelectrical impedance analysis).

Predicate Device:
TANITA Body Fat Analyzer Model TBF-105
K930599

Scientific Concepts and Significant Performance Characteristics:

	Body Fat Analyzer Model TBF-105 K930599	TANITA Body Fat Analyzer TBF/BF/ Ultimate Scale
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 using BIA (bioelectrical impedance analysis).
PRODUCT DESCRIPTION:	Body composition analyzer/scales utilize a "foot-to-foot" BIA (bio-electrical impedance) technology to determine internal body composition.	Body composition analyzer/scales utilize a "foot-to-foot" BIA (bio-electrical impedance) technology to determine internal body composition.
ANALYTICAL METHOD/MEASUREMENT	▪ "Foot-to-Foot" BIA • Patented in-house BIA and DEXA reference methods	▪ "Foot-to-Foot" BIA ▪ Patented 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 Body Fat Analyzer TBF/ BF/ Ultimate Scale to the predicate device Body Fat Analyzer Model TBF-105 clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device.

Based on the results of using the previously approved "Foot-to-Foot" BIA methodology with our patented in-house BIA it was concluded that the TANITA Body Fat Analyzer(s) TBF/BF/Ultimate Scales perform as well as the predicate device and therefore have proven its safety and efficacy.

Carol Alloian (Benson)
TANITA Corporation of America
Manager
Regulatory Affairs Manager
Phone: (847) 640-9251 ext. 116
Fax: (847) 640-7978

November 30, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2002

Ms. Carol Alloian (Benson)
Regulatory Affairs Manager
TANITA Corporation of America
2625 South Clearbrook Drive
ARLINGTON HEIGHTS IL 60005

Re: K014009
Trade/Device Name: Body Fat Analyzer, Professional Series: Models TBF-300A, TBF-310, TBF-410, TBF-215, and BF-350; Consumer Body Fat Monitor/Scale Series: Models TBF-611, TBF-612, TBF-621, TBF-622, BF-623, BF-625, BF-626, BF-541, BF-555, BF-542, TBF-551, BF-556, BF-558, BF-559, BF-572, TBF-521
Ultimate Scales 2000, 2001, and 2001T
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: March 25, 2002
Received: March 26, 2002

Dear Ms. Alloian:

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 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 this 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" (21 CFR Part 807.97). 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 (if known): K014009

Device Name: Tanita Body Fat Analyzer

Indications for Use:

MODELS TBF-300A, TBF-310, TBF-410, TBF-215, BF-350:

A body composition analyzer that measures body weight and impedance and estimates body fat percent, BMI, fat mass, fat free mass, basal metabolic rate, and total body water using BIA (bioelectrical impedance analysis).

MODELS TBF-611, TBF-612, TBF-621, TBF-622, BF-623, BF-625, BF-626, BF-541, BF-555, BF-542, TBF-551, BF-556, BF-558, BF-559, BF-572, TBF-521, Ultimate Scale 2001:

A body composition analyzer that measures body weight and impedance and estimates body fat percent using BIA (bioelectrical impedance analysis).

(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)

David G. Seyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014009