APR 15 2011

510(k) Summary

The following information is provided in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92

1. Submitter: Tanita Corporation
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   Tokyo 174-8630 Japan
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   Data of summary: April 13, 2011

2. Name of the Device: MC-180MA Multi-frequency Body Composition Analyzer
   Trade / Proprietary Name: MC-180MA Multi-frequency Body Composition Analyzer
   Common or Usual Name: Body Composition Analyzer
   Classification Name: Analyzer, Body Composition
   21 CFR §870.2770
   Class II
   Product Code: MNW

3. Predicate devices to claim substantial equivalence:

   a. Tanita Model BC-418 Segmental Body Composition Analyzer—K033157
   b. Biospace Model InBody 3.0 Body Composition Analyzer—K042528
   c. Tanita Model SC-331 Body Composition Analyzer—K090479

4. Description of the Device:

   The Tanita Model MC-180MA Multi-frequency Body Composition Analyzer is a computer-operated body composition analyzer that utilizes bioelectrical impedance analysis (BIA) to estimate body composition of fat, muscle and bone, water compartments, and basal metabolic rate (BMR).

   Actual measurements made by the MC-180MA include body weight and bioelectrical impedance. BIA is used to make estimates based upon these measured values.

5. Intended Use Statement:

   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 and

segmental fat percent and weight, total body water percent and weight, intracellular and extracellular water weight, total body and segmental muscle mass, physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate (BMR), and fat free mass (FFM), 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.

For subjects 17 years old and younger, only fat % is displayed.

6. Summary of technological characteristics compared to predicate devices:

Both the Tanita Model MC-180MA and predicate devices (Item 3 above) are intended for use to measure weight and bioelectrical impedance, and estimate body composition (fat, muscle, bone and water) by BIA in healthy children and in healthy adults.

The technology underlying BIA estimation for the Model MC-180MA and predicate devices is the same. Design considerations—computer-operation with visual-display user interface; use of multiple-regression algorithms to predict body composition based upon body weight and segmental bioelectrical impedance measurements—and energy-source considerations—multipolar surface electrodes; alternating current in the 5- to 500-kilohertz range at levels of 90 microamperes (Tanita models) to 250 microamperes (Biospace model)—are the same. Multiple-frequency measurement of bioelectrical impedence values used in estimation of percent fat, fat-free mass, total body water and extracellular water was verified in clinical testing.

Comparison of these intended-use and technological characteristics demonstrate that the Model MC-180MA is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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

APR 15 2011

Re: K100183
Trade/Device Name: Tanita MC-180MA Multi-frequency Body Composition Analyzer
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: April 13, 2011
Received: April 14, 2011

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. 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 Statement

510(k) Number (if known): K100183

Device Name: Tanita MC-180MA Multi-frequency
Body Composition Analyzer

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 and segmental fat percent and weight, total body water percent and weight, intracellular and extracellular water weight, total body and segmental muscle mass, physique rating, bone mass, visceral fat rating with healthy range, basal metabolic rate (BMR), and fat free mass (FFM), using BIA (Bioelectrical Impedance Analysis).

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For subjects 17 years old and younger, only fat % is displayed.

(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 _____X_____
(Per 21 CFR §801.109)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K100183