Section 5. 510(k) Summary (21 CFR 807.92)

Date prepared: August 22, 2013

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SEP 26 2013

Proprietary name:
Precision One Lifecare and Detecto Body Fat scales
Common name:
Body fat scale
Classified name:
Body composition analyzer
CFR 870.2770 Product code: MNW

Intended use:
The Precision One Lifecare and Detecto body fat scales measure weight and use bioelectrical impedance analysis (BIA) technology to estimate and keep a record of body fat percent, total body water percent, bone mass percent, and muscle mass percent. The scales also provide a daily calorie intake recommendation and a fitness assessment. The scales are intended for use in the home/domestic setting only.

Estimated body fat percent is intended for use on individuals 7-17 years old (Healthy Children) and 18-80 years old (Healthy Adults).

Estimated body water percent, estimated muscle mass percent, estimated bone mass percent, and calorie intake are intended for use on individuals 18-80 years old.

Children under 7 years old and adults over 80 years old can use the scales for normal weighing mode only.

The scales are not intended for diagnosis.

The specific model names and numbers for these scales are:
Precision One Lifecare model numbers – 7853, 7840, 7841, 7850, 7851, and 7856.
Detecto model numbers – D221, D222, D223, D212, D207, D201, D202, D203, D204, and D205

Substantial equivalence:
The Precision One Lifecare and Detecto Body Fat scales are substantially equivalent to:
Tanita Model: SC331 – Body Composition Analyzer (K090479)

Models:
Precision One Lifecare

- Removable Remote Glass LCD Digital Body Fat/Body Composition: 7 in 1 Analysis, Model 7853 (EF932)
- Glass LCD Digital Body Composition: 3 in 1 Analysis, Model 7840, 7841 (EF9621)
- LCD Digital Body Fat/Body Composition: 5 in 1 Analysis, Model 7850 (EF151)
- Glass LCD Digital Body Fat/Body Composition: 7 in 1 Analysis, Model 7851 (EF941)
- Stainless Steel LCD Digital Body Fat/Body Composition: 5 in 1 Analysis, Model 7856 (EF432)

Detecto

- Glass LCD Digital Body Composition: 6 in 1 Analysis, Models D221 (EF971), D222 (EF972), D223 (EF973)
- Glass LCD Digital Body Composition: 6 in 1 Analysis, Model D212 (EF962)
- Wide Body Glass LCD Digital Body Fat/Body Composition: 7 in 1 Analysis, Model D207 (EF934)
- LCD Digital Body Fat/Body Composition: 7 in 1 Analysis, Model D201 (EF921/H)
- Heavy Duty Glass LCD Digital Body Fat/Body Composition: 7 in 1 Analysis, Model D202 (EF541)
- Glass LCD Digital Body Fat/Body Composition: 5 in 1 Analysis, Model D203 (EF906)
- Stainless Steel Body Composition: 5 in 1 Analysis, Model D204 (EF432)
- Wide Body Glass LCD Digital Body Fat/Body Composition: 7 in 1 Analysis, Model D205 (EF922)

Device description
The following device description pertains to all models.

- The Body Fat scales use BIA (Bio Impedance Analysis) technology which passes an electrical current through the body to estimate body fat percent, muscle percent, body water percent, and bone percent. The electrical current is small and may not be felt. Contact with the body is made via glass and stainless steel pads on the platform of the analyzer.

- The devices are single frequency electrical bio-impedance analyzer. All models measure current, voltage and phase angle, calculate impedance, resistance and reactance. These measurements and calculations are used to estimate the body composition of: body fat percent, body water percent, muscle mass percent, bone mass percent, daily calories intake recommendation, and provides a fitness assessment. All models have a bi-polar set of contact electrodes which are attached to stainless steel pads on the platform of the analyzer.

- The scales can store the personal data of up to 12 users. As well as being an analyzer, these devices can be used as a conventional scale. The models have one operating mode: Algorithm Mode.

- Algorithm Mode: Displays estimates of body fat percent and body water percent. The devices compute these values using accepted peered reviewed published algorithms tailored to the candidate types: general population of the accepted age ranges of adult or children.

- The devices consist of a main unit having a glass or stainless steel platform for the user to step on. On the platform, 2 stainless steel electrodes are mounted which are connected to the electronics circuitry with the analyzing MCU. When the user steps on the electrodes (1 for each foot) a small current of about 90μA will pass through the user body through the 2 feet to complete the close circuitry in order for the analyzer to measure and capture the electrical data change in terms of Bio electrical impedance, resistance, reactance, taking into account other parameters as to personal data of Age, Height, Gender, and Weight.

Summary of technological characteristics compared to predicate devices
The Body Fat scales and Tanita Model SC331 (K090479) are intended for use to measure weight, bioelectrical impedance, and estimate body composition (fat, muscle, bone and water) by BIA in a healthy individual.

The technology underlying BIA estimation for the Body Fat scales and Tanita Model SC-331 (K090479) is the same. Design considerations – software design, with LCD visual display, use of multiple regression algorithms to predict body composition based upon body weight, bioelectrical impedance measurements, energy source consideration, multi-polar surface electrodes, electrical current in 5 – to 50 kilohertz range at levels of 90 microamperes to 250 microamperes – are the same.

Comparison of these intended and technological characteristics demonstrate that Body Fat scales are substantially equivalent to the predicate device.

The following table provides a comparison of features to the predicate.

Feature	Subject Device: Body Fat scales	Predicate Device: Tanita Body Composition Analyser Model: SC-331
510(k) Number		K090479
Sponsor	Precision One Lifecare., Ltd.	Tanita Corporation
Weighing Technology	Strained Gauge Load Cell	Stained Gauge Load Cell
Weight Capacity	150 kg / 330 lb 180 kg / 400 lb 200 kg / 440 lb	270 kg / 600 lb
Device Description	Utilizes a "foot-to-foot" bioelectrical impedance analysis (BIA) technology to determine internal body composition.	Utilizes a "foot-to-foot" bioelectrical impedance (BIA) technology to determine internal body composition.
Analysis Method	BIA (Bioelectrical Impedance Analysis)	BIA (Bioelectrical Impedance Analysis)
BMI Measurement	NA	Yes
Input Item: Age Range Gender Height Range	7 – 99 years (1 yr increment Male & Female 100–250 cm / 3.03 ft–7 ft 11.5"	5- 99 years (1 year Increment) Male & Female 90 – 249.9 cm / 3 ft – 7 ft 11.5"
Operating Frequency Range	50KHz	50KHz
Power Source	2*AAA (3 Volt DC) 1 or 2 Li CR2032 batteries (3 Volt DC)	AC – DC adaptor of Input 100-240Vac 50/60 hz, 1.5 A converted to 7Volt DC output to the device
Measuring current (A)	90μA	90μA
Contact Electrodes	Bi-polar	Tetra-polar
Measuring Impedance Range	150 – 1200 Ω	150 – 1200 Ω
Operating Keys	3 or 4 keys 1 key: Setting & real time clock 1 key: Alarm on/setting, upward increase scrolling. 1 key: Weight Mode, downward decrease scrolling 1 key: Memory recall comparison mode. Start mode for measuring Body Composition.	1 key for printer 1 key for clothing weight. 1 key for mode selection between Body Composition & Weight Only. 1 key for selection of lb or kg 1 key for setting date/time to printer. 4 keys for setting Body Type: Standard, Athlete, Male, Female. 11 keys for numeric input 1 key for clear / cancel Total 21 keys
Measuring/Weighing Platform	Glass	Plastic
Number of Electrodes	2 or 4	4

Testing

The Body Fat Scales were tested by an independent laboratory for compliance to the requirements of IEC 60601-1 (electrical safety) and IEC 60601-1-2 (EMC). Test results showed compliance.

The performance of Body Fat Scales was compared to the performance of the predicate device through testing conducted by the sponsor. This testing consisted of 70 participants (50 adults and 20 children) standing on both the predicate scale and a Body Fat scale to obtain measureable parameters which are also used for algorithm calculations. This testing showed the two scales provide substantially equivalent results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 26, 2013

Precision One Lifecare, Ltd.
% Steven Chernoff
Vice President
Drug & Device Development Co., Inc.
P.O. Box 3515
Redmond, WA 98073

Re: K130952
Trade/Device Name: Precision One Lifecare and Detecto Body Fat scales
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: August 22, 2013
Received: August 26, 2013

Dear Steven Chernoff,

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 -S

Acting for:
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Premarket Notification

Section 4 – Indications for Use Statement

Indications for Use

510(k) Number (if known): K130952

Device Name: Precision One Lifecare and Detecto Body Fat scales

Indications for Use

The Precision One Lifecare and Detecto Body Fat scales measure weight and use bioelectrical impedance analysis (BIA) technology to estimate and keep a record of body fat percent, total body water percent, bone mass percent, and muscle mass percent. The scales also provide a daily calorie intake recommendation and a fitness assessment. The scales are intended for use in the home/domestic setting only.

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Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (Part 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)

Herbert P. Lerner -S