510(k) Summary

CONFIDENTIAL

Scaleman Body Fat Scales

MAY 12 2009

Submitter Name:	Fook Tin Technologies Ltd.
Submitter Address:	4/F Eastern Center, 1065 King's Road, Quarry Bay, Hong Kong
Contact Person:	Dr. John Chai, Managing Director
Phone Number:	(852) 2960 7288
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Date:	October 30, 2008
Device Trade Name:	Scaleman Body Fat Scales
Device Common Name:	Impedance plethysmograph (body composition analyzer/scales)
Classification Name:	Impedance plethysmograph
Classification Number:	21 CFR 870.2770
Product code:	MNW
Predicate Device:	Tanita Innerscan Body Composition Monitor, K040778
Statement of Intended Use:	The Scaleman Body Fat Scales – Models in "Family Model List 1A" is a series of body composition analyzers that measure body weight and impedance and estimate percentage of body fat and body water using BIA (bioelectrical impedance analysis). They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment. The Scaleman Body Fat Scales - Models in "Family Model List 1B" is a series of body composition analyzers that measure body weight and

impedance and estimate percentage of body fat and body water, bone mass and muscle mass using BIA (bioelectrical impedance analysis). They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.

Device Description, Summary of Technological Characteristics, and Comparison to the Predicate Device

The models in Scaleman body fat scales' Family Model List 1A and 1B submitted in this 510(k) are body composition analyzers. The devices estimate percentages of body fat, body water, bone mass and muscle mass (as noted in the indications statement) based on bioelectrical impedance analysis (BIA). The following table illustrates the substantial equivalence in technology and intended use to the predicate device.

Feature	Proposed Device: Scaleman Body Fat Scales (Model FS-148BW1)	Predicate Device: Tanita InnerScan Body Composition Monitor (Model BC-533)
510(k) Number	NIL	K040778
Manufacturer	Fook Tin Technologies Ltd.	Tanita Corp of America
Classification # Product code	21 CFR 870.2770 MNW	21 CFR 870.2770 MNW
Indication for use	The Scaleman Body Fat Scales – Models in "Family Model List 1A" is a series of body composition analyzers that measure body weight and impedance and estimate percentage of body fat and body water using BIA (bioelectrical impedance analysis). They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment. The Scaleman Body Fat Scales - Models in "Family Model List 1B" is a series of body composition analyzers	The Tanita family of InnerScan Body Composition Monitors measure body weight and impedance and estimate percentage of body fat and body water, visceral fat rating, bone mass, muscle mass, physique rating, daily calorie intake (DCI) and metabolic age using BIA. They are intended for use by healthy children 7-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.

	that measure body weight and impedance and estimate percentage of body fat and body water, bone mass and muscle mass using BIA (bioelectrical impedance analysis). They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.	
Device description	Body composition analyzer/scale that utilizes a "foot-to-foot" bioelectrical impedance (BIA) technology to determine internal body composition.	Body composition analyzer/scale that utilizes a "foot-to-foot" bioelectrical impedance (BIA) technology to determine internal body composition.
Analysis method	BIA	BIA
Operating parameters	50 KHz	50 KHz
Power source	Replaceable 9V or CR2032 or AAA batteries, depending on the model	AA batteries
Operating keys	Range of 3 to 6, depending on the model	13
Number of electrodes	4 or 2	4
Clinical performance	A comparative clinical study, submitted in this notification (Section 20), showed that body fat (%) and FFM (kg) in normal and athlete modes, body water (%), muscle mass (kg), bone mass (kg) and weight (kg) measured or estimated by test and predicate devices were significantly correlated (P<.05).	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2009

Fook Tin Technologies Ltd
c/o Dr. John Chai
Managing Director
4/F Eastern Center
1065 King's Road
Quarry Bay, Hong Kong

Re: K083838
Trade/Device Name: Scaleman Body Fat Scales
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II (two)
Product Codes: MNW
Dated: April 18, 2009
Received: May 5, 2009

Dear Dr. Chai:

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 such 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083838

Device Name: Scaleman

Indications For Use:

Family Model List 1A

A series of body composition analyzers that measure body weight and impedance and estimate percentage of body fat and body water, using BIA (bioelectrical impedance analysis).

They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.

Family Model List 1B

A series of body composition analyzers that measure body weight and impedance and estimate percentage of body fat and body water, bone mass and muscle mass using BIA (bioelectrical impedance analysis).

They are intended for use by healthy children 10-17 years old and healthy adults with active, moderately active, to inactive lifestyles for body composition assessment in the home environment.

Prescription Use NO (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use YES (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)

Donna R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083838