8.0 PREMARKET NOTIFICATION 510(K) SUMMARY

MAY - 2 2003

Sponsor	Bonso Electronics International Inc. 1919 Yacht Colnia Newport Beach CA 92660
Contact Person	Mr. George O'Leary, Director
Phone	949-760-7611
Fax	949-760-7607
Email	goleary@worldnet.att.net

Device Name

Trade Name of Device	Healthometer Professional Body Fat Monitor and Scale (Models BFM940, BFM945, and BFM960)
Common Name	Body Fat Analyzer
Classification name	Analyzer, Body Composition
Product Code	MNW
Regulation Class	Class II
Regulation Number	§870.2770

Indications for Use

The Healthometer Professional Body Fat Monitor and Scale is indicated to measure body weight and impedance and estimate body fat percent.

Device Description

The Bonso BFM is a portable device for measuring the percentage of body fat in human subjects. The device includes a platform-type weighing scale that utilizes internal strain gauges to electronically measure the weight of a subject standing on the scale platform.

Basis for Substantial Equivalence

Predicate Device	Tanita BF-625/BF-626
510(k) #	K014009
Sponsor	Tanita Corp. of America 2625 South Clearbrook Drive Arlington Heights, IL 60005

The 510(k) contains extensive bench data demonstrating that the Bonso device performs as labeled. Additionally, testing directly comparing the Bonso and the predicate device was provided. This testing showed that the Healthometer Professional Body Fat Monitor and Scale is substantially equivalent to the Tanita BF-625/BF-626 that is also indicated for use to measure body weight and impedance and estimate body fat percent using the BIA method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2003

Bonso Electronics Int'l., Inc.
c/o Russell P. Pagano, Ph.D.
Vice President
M Squared Associates, Inc.
719 A Street, N.E.
WASHINGTON DC 20002

Re: K030349
Trade/Device Name: Healthometer Professional Body Fat Monitor and Scale
Models BFM 940, BFM 945, and BFM 960
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 74 MNW
Dated: January 31, 2003
Received: February 3, 2003

Dear Dr. Pagano:

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): K030349

Device Name: The Healthometer Professional Body Fat Monitor and Scale Models BFM 940, BFM 945, and BFM 960

Indications For Use: The Bonso Electronics Int'l., Inc., Healthometer Professional Body Fat Monitor and Scale Models BFM 940, BFM 945, and BFM 960 are indicated to measure body weight and impedance and estimate body fat percent.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030349

(Optional Format 3-10-98)

Over-the-Counter Use ✓