

**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**

<b>Predicate Device</b>	Tanita BF-625/BF-626
510(k) #	K014009
<b>Sponsor</b>	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.



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  
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

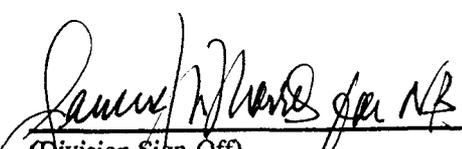
Device Name: The Healthometer Professional Body Fat Monitor and Scale Models BFM 940, BFM 945, and BFM 960

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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K030349

Over-the-Counter Use