JUN 27 2006

Section 5 – 510(k) Summary

The following is the 510(K) summary in accordance with 21CFR807.87(h)

SUBMITTER INFORMATION

Company Name:	Life Measurement, Inc.
Establishment Registration Number:	3003873943
Company Address:	1850 Bates Avenue Concord, CA 94520
Company Phone:	(925) 676-6002
Company Facsimile:	(925) 676-6005
Contact Person:	Michael Sullivan Vice President of Operations

DEVICE IDENTIFICATION

Device Trade Name:	Sonamet Body Composition Analyzer **Note : The trade name for the original Sonamet Body Composition analyzer is currently the "BOD POD". This will remain unchanged.**
Device Generic Name:	Body Composition Analyzer
Device Classification:	Classification code: 21 CFR 870.2770 Code MNW
Classification Panel	Cardiovascular

IDENTIFICATION OF PREDICATE DEVICES

The Sonamet Body Composition System is substantially equivalent to the following devices, which have received FDA clearance:

Device Name	Manufacturer	K Number
Sonamet Body Composition Analyzer	Life Measurement, Inc.	K924972
TANITA Segmental Body Composition Analyzer Model BC-418	TANITA Corporation of America	K033157

The technological characteristics of the Sonamet Body Composition System have not been changed. The method of calculating RMR using values of Fat Free Mass and Fat Mass is similar to the methods used by the TANITA Model BC-418 unit to calculate Basal Metabolic Rate.

DEVICE DESCRIPTION

The Sonamet Body Composition System is designed to measure the mass and estimate the body composition of individuals. Once an individual's body composition has been determined, the BOD POD is able to accurately estimate Resting Metabolic Rate (RMR) and total Energy Expenditure (TEE).

The BOD POD estimates body composition using a densiometric approach (i.e. by determining the density of the entire body). A weighing apparatus is used to measure the subject's mass. Air displacement plethysmography is used to measure the subject's volume. Using this data, the subject's density is calculated. The subject's body composition is then estimated using several algorithms derived from scientific research.

An individual's RMR and TEE can also be estimated accurately using values for Fat Mass and Fat Free Mass. Scientifically derived algorithms utilize the Fat Mass and Fat Free mass values determined by the BOD POD to calculate RMR and TEE.

INTENDED USE

The BOD POD® is indicated for measuring the body mass and estimating the body composition (i.e. percent and absolute amounts of fat and lean body mass) of generally healthy individuals. The BOD POD is also indicated for estimating Resting Metabolic Rate (RMR) and Total Energy Expenditure (TEE) in generally healthy individuals aged 18 years or older.

CONCLUSIONS DRAWN FROM STUDIES

The results of verification testing demonstrate that the RMR and TEE results generated by the BOD POD Body Composition Analyzer are accurate when compared with expected results based on published scientific research, and is substantially equivalent to the predicate devices. Test results indicate that the device satisfies functional performance requirements safely and accurately when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Alex Urlando
Vice President, Operations
Life Measurement, Inc.
1850 Bates Avenue
CONCORD, CA 94520

MAY - 1 2007

Re: K060848
Trade/Device Name: BOD POD® Sonamet Body Composition Analyzer [modified indications]
Regulation Number: 21 CFR§870.2770
Regulation Name: Air Displacement Plethysmograph for Body Composition Analysis
Regulatory Class: Class II
Product Code: OAC
Dated: March 23, 2006
Received: March 31, 2006

Dear Mr. Urlando:

This letter corrects our substantially equivalent letter of June 27, 2006.

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 (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 continue 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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/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

Indications for Use

510(k) Number (if known): K060848

Device Name: Sonamet Body Composition Analyzer (BOD POD)

Indications For Use:

The BOD POD® is indicated for measuring the body mass and estimating the body composition (i.e. percent and absolute amounts of fat and lean bod[illegible] healthy individuals. The BOD POD is also indicated for estimating [illegible] Rate (RMR) and Total Energy Expenditure (TEE) in generally healthy individuals aged 18 years or older.

Prescription Use _____ AND/OR Over-The-Counter Use [illegible]
(Part 21 CFR 801 Subpart D) (21 CFR 8[illegible])

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON [illegible] NEEDED)

Concurrence of CDRH, Office of Device Evaluatio[illegible]

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060848

(vers 6/25/05)