MAR - 1 2004

K032610
page 1 of 2

Section 6 – 510(k) Summary

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:	Modified Sonamet Body Composition Analyzer **Note : The trade name for the original Sonamet Body Composition analyzer is currently the "BOD POD ". The modified version will be referred to as the "PEA POD – Infant Body Composition System" when it is introduced into the market.**
Device Generic Name:	Body Composition Analyzer
Device Classification:	Classification code: 21 CFR 870.2770 Code MNW
Classification Panel	Cardiovascular

IDENTIFICATION OF PREDICATE DEVICES

The modified 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
EM- SCAN HP-2 Pediatric Body Composition Analyzer	EM-SCAN, Inc.	K902042

The intended use and technological characteristics of the modified Sonamet Body Composition System are the same as the above predicate devices. Modifications for the pediatric use indication do not raise additional questions regarding safety and efficacy.

DEVICE DESCRIPTION

The modified Sonamet Body Composition System ("The PEA POD") is designed to measure the mass and estimate the body composition of infants with body weights ranging between 1 and 8 kilograms, who do not require life support. The PEA 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. The device components are housed in a movable cart, which contains the reference chamber, calibration volume, air circulation system, Air Temperature Control System, electronic components, printer and CPU.

INTENDED USE

The modified Sonamet Body Composition Analyzer, also known as the PEA POD® Infant Body Composition System (the PEA POD), is indicated for measuring body mass and estimating the body composition (i.e., the body fat and lean body mass) of infants between 1 and 8 kilograms. It is not intended for use with infants requiring life support.

CONCLUSIONS DRAWN FROM STUDIES

The results of verification testing demonstrate that the PEA POD Body Composition Analyzer 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

MAR - 1 2004

Life Measurement, Inc.
c/o Dr. Sheila Pickering
2081 Longden Circle
LOS ALTOS CA 94024

Re: K032610
Trade/Device Name: Modified Sonamet Body Composition Analyzer (PEA POD)
Regulation Number: 21 CFR §870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: 78 MNW
Dated: January 5, 2004
Received: January 9, 2004

Dear Dr. Pickering:

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 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 one of the following numbers, based on the regulation number at the top of the 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" (21CFR Part 807.97) you may obtain. 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

ATTACHMENT 14

FDA Submission Cover Sheet

510(k) Number: K032610

Device Name: Modified Sonamet Body Composition Analyzer

Indication For Use:

The modified Sonamet Body Composition Analyzer, also known as the PEA POD® Infant Body Composition System (the PEA POD), is indicated for measuring body mass and estimating the body composition (i.e., the body fat and lean body mass) of infants between 1 and 8 kilograms. It is not intended for use with infants requiring life support.

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

_____Concurrence Of CDRH, Office Of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ___✓___
(Per 21CFR 801)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032610