



LIFE MEASUREMENT, INC

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Standards and Regulations (HFZ-84)  
5600 Fishers Lane  
Rockville, MD 20857

March 21, 2005

Dear Sir or Madam:

Life Measurement Inc., according to section 513 (e) of the Federal Food, Drug, and Cosmetic "Act", as amended, is requesting a review of the classification of its Sonamet Body Composition Analyzer (the "BOD POD") and Modified Sonamet Body Composition Analyzer (the "PEAPOD") devices. We believe that our BOD POD and PEA POD devices, which are based on air displacement plethysmography technology, should be given its own product code rather than be included with body composition analyzers based upon impedance plethysmograph technology. Therefore, we are requesting the creation of a new product code for air displacement plethysmography. It is also requested that the BODPOD and PEAPOD devices be reclassified from Class II devices to Class I devices.

Information supporting our application is attached. If there are any questions regarding this application please do not hesitate to contact me at 925-676-6002, or at [msullivan@bodpod.com](mailto:msullivan@bodpod.com)

Sincerely Yours,

Michael Sullivan  
Vice President, Operations  
Life Measurement, Inc.

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## General Background Information

The Sonamet Body Composition Analyzer, or "BOD POD", is a device that received 510K approval on February 13<sup>th</sup> 1995 (K924972). Approval was based on substantial equivalency to the hydrostatic weighing method of body density measurement, as well as equivalency to the total body plethysmography method of determining thoracic gas volume. The 510K approval letter received from CDRH, shown in Appendix A, did not indicate a classification for the BOD POD, stating it was "UNCLASSIFIED" but assigned it to Procode 78 MNW.

The Modified Sonamet Body Composition Analyzer, or "PEAPOD" was determined to be substantially equivalent to the BOD POD and received 510K approval on March 1, 2004 (K032610). The PEA POD 510K approval letter from the CDRH stated that the PEA POD was a Class II device. A copy of the approval letter is also included in Appendix A.

Both devices are used to estimate the body composition of an individual using air displacement plethysmography (ADP) to determine the individual's body density. The difference between the units is that the PEAPOD is specifically designed to accommodate test subjects between 1 and 8 kg in weight, while the BOD POD is designed to accommodate larger subjects. Appendix B includes the Operator's Manual for the BOD POD, which contains information about the basic operating principles of the BOD POD (pages 8 – 11), as well as the specifications of the BOD POD device (page 4).

## **Reasons for requesting a New Product Category Classification for the BOD POD**

Currently, the BOD POD is classified in product category MNW, 870.2770 (Impedance Plethysmography). The description of this category describes impedance plethysmography as “a device used to estimate peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs”. All body fat analyzers and scales listed in this category, except for the BOD POD, utilize impedance plethysmography technology in their products. The underlying technology of the BOD POD, air displacement plethysmography, is completely different than impedance plethysmography. In concise terms, the BOD POD utilizes Boyle’s law ( $P_1V_1 = P_2V_2$ ) and the measurement of small pressure changes in the test chamber, created by induced volume changes, to calculate an individual’s body volume. Impedance plethysmography uses the conductance of alternating electrical current in body water to estimate body water compartments and body composition. Appendix C includes a copy of the CDRH website pages showing the Device Listings for product code 78 MNW as well as the definition for Title 21, Subchapter H, Part 870, Subpart C, section 870.2770.

Given that there is no similarity at all between the impedance plethysmography technology and ADP, we believe that the BOD POD should be removed from Product Class 78 MNW and placed in a more appropriate category. Since there does not appear to be an existing classification that seems appropriate for ADP, we are requesting that consideration be given to create a new product category for ADP technology and its use in the analysis of body composition. The BOD POD determines an individual’s body density in the process of determining body composition, similar to the process of Hydrostatic weighing. A better generic description for the BOD POD would be air displacement plethysmography, or perhaps a Densitometer. A more accurate product code description will allow a more appropriate and equitable review of the BOD POD’s risk classification to be made.

Appendix D includes copies of published studies and trials that establish clearly that the ADP technology of the BOD POD is significantly different than impedance plethysmography, and support our contention that the BOD POD is in the wrong product classification. The following studies are included for your review:

- Goodpaster, Bret H., “Measuring Body Fat Distribution and Content in Humans”, Lippincott Williams & Wilkins, 2002
- Fields, David “Body Composition Assessment via Air-Displacement Plethysmography in Adults and Children: a Review”, American Journal of Nutrition, 2002
- Miyatake, N. , “ A New Air Displacement Plethysmograph for the Determination of Japanese Body Composition, Blackwell Science, 1999
- Flakoll, Paul, “Bioelectric Impedance vs Air Displacement Plethysmography and Dual- Energy X-ray Absorptiometry to Determine Body Composition in Patients with End-Stage Renal Disease”, Journal of Parenteral and Enteral Nutrition, 2003

- Ellis, Kenneth J., “Innovative Non- or Minimally-Invasive Technologies for Monitoring Health and Nutritional Status in Mothers and Young Children”, American Society for Nutritional Sciences, 2001

## **Justification for Reclassification of the BOD POD from Class II to Class I**

In addition to establishing a new product code for the BOD POD, we are also petitioning to have the BOD POD classified as a Class I device. We believe the BOD POD should be classified as a Class 1 device for the following reasons:

- The BOD POD has been placed in category MNW, 870.2770, Impedance Plethysmograph. This category does not accurately describe the properties of the BOD POD, since the underlying principles of the BOD POD is air displacement plethysmography, not impedance. The BOD POD should have its own category that reflects its use of air displacement plethysmography.
- Our review of the BOD POD and PEA POD compared with the General Device Classification Questionnaire (Form FDA 3429 (2/97)) of section 860.3 indicates that the BOD POD and PEA POD should be classified as Class 1 devices
- The historical track record of the BOD POD has validated that the safety and effectiveness of the device is such that a Class I classification is warranted
- The BOD POD is not a device that poses a threat to the user in the event of the device failing to perform properly. The design of the device allows the unit to be in a “safe state” in the event of a power failure.
- Our recent application to the EU authorities for approval to sell the PEA POD as a medical device within the EU determined that the PEA POD is a Class 1 device. This determination was based upon the application of the device classification rules described in the MDD

Over the 10 years the BOD POD has been on the market, there has never been a reported incident where an individual has been injured using the BOD POD. The operator’s Manual in Appendix B has information regarding the physical description of the BOD POD and its specifications, as well as the listed warnings and contraindications for its use. This information is also listed on the enclosed form FDA 3427 (2/97).

We believe that the BOD POD was not classified properly from the very beginning; in fact, the 510 K approval letter lists the unit as “UNCLASSIFIED”. We were not actually informed of the exact classification of the device, as we only found out that the classification was made Class II after visiting the CDRH website several years later. The BOD POD is a unique device that might not have been clearly understood when the initial application was made. However, with 10 years of operational field data and experience to review, it is clear that the BOD POD is a low risk, Class I device. Unlike impedance plethysmography, there is no intended energy (i.e. electrical current used for bioimpedance technology) transferred to the subject being measured. The changes in pressure that occur in the BOD POD are very small, less than 2 cm H<sub>2</sub>O. The other devices in classification 870.2770 all pass low amounts of electrical energy through the test subject, which makes these devices more risky than the BOD POD. Also, studies have shown that the BOD POD is consistently more effective than bioimpedance plethysmography in determining an estimate for body composition. By putting the BOD

POD in the same device class as bioimpedance plethysmography, this would lead someone to believe that the BOD POD has identical levels of safety and effectiveness as the bioimpedance devices in the category, which is not accurate.

## Determination of Safety and Effectiveness

In the previous section we presented the BOD POD's impressive safety record since inception. Appendix E includes several studies that demonstrate the safety and effectiveness of the BOD POD versus other methods of body composition measurement, including impedance plethysmography. These studies show that for a variety of subject populations, the BOD POD is consistently more effective than other methods, with the effectiveness being such that the BOD POD has been used in some studies as the "reference device" for body composition determination.

The following published studies, found in Appendix E, support the BOD POD as being safe and effective for various populations, including those with special medical conditions such as pregnancy and populations requiring special considerations such as children:

- Yee, Alice, "Calibration and Validation of an Air-Displacement Plethysmography Method for Estimating Percentage Body Fat in an Elderly Population: a Comparison Among Compartmental Models", American Journal of Clinical Nutrition, 2001
- McCarthy, Elizabeth A. , "Determination of Maternal Body Composition in Pregnancy and its Relevance to Perinatal Outcomes", Obstetrical and Gynecological Survey, 2004
- Petroni, M.L., "Feasibility of Air Plethysmography (BOD POD) in Morbid Obesity: a Pilot Study", Acta Diabetol, 2003
- Weyers, Anna M. " Comparison of Methods for Assessing Body Composition Changes During Weight Loss", Medicine and Science in Sports & Exercise, 2002
- Nicholson, Jennifer C., "Estimation of Body Fatness by Air Displacement Plethysmography in African American and White Children", pediatric research, 2001
- Gartner, A. "Use of Hand-to-Hand Impedancemetry to Predict Body Composition of African Women as Measured by Air Displacement Plethysmography", European Journal of Clinical Nutrition, 2004
- Gomez –Ambrosi, Javier, "Involvement of Leptin in the Association Between Percentage of Body Fat and Cardiovascular Risk Factors", Clinical Biochemistry, 2002

## Conclusion

We believe that the current Product Code assigned to the BOD POD is not representative of air displacement plethysmography. We are requesting that a new Product Code be established specifically for Air Displacement plethysmography. We also take the position that the BOD POD and the substantially equivalent PEA POD device both be reclassified as Class I devices from their current Class II classification. The design of the BOD POD, the air displacement plethysmography technology, and the 10 year safety and effectiveness record of the BOD POD in the field all support that the BOD POD is a low risk device and that the Class I designation is more appropriate.

Data presented in support of our petition includes:

- Completed classification questionnaire and supplemental data sheet which indicate that the BOD POD should be a Class I device
- Description of ADP technology compared with Impedance Plethysmography, highlighting the differences that warrant the creation of a new Product Code for ADP
- BOD POD Operator's Manual which demonstrates the safety features and the ease of use of the BOD POD
- Various published studies that demonstrate the superiority of the BOD POD in the areas of safety and effectiveness, compared with Bioimpedance Plethysmography.

**GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE**

PANEL MEMBER / PETITIONER

*Michael Sullivan, VP Operations, Life Measurement Inc.*

DATE

*3/9/05*

GENERIC TYPE OF DEVICE

*Air Displacement Plethysmography (BOD POD BODY COMPOSITION ANALYZER)*

CLASSIFICATION RECOMMENDATION

*Reclassify to Class I*

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?

YES  NO

Go to Item 2.

2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?

YES  NO

Go to Item 3.

3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?

YES  NO

Go to Item 4.

4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?

YES  NO

If "Yes," go to Item 6.  
If "No," go to Item 5.

5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?

YES  NO

If "Yes," Classify in Class I.  
If "No," go to Item 6.

6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH SPECIAL CONTROLS IN ADDITION TO GENERAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?

YES  NO

If "Yes," Classify in Class II and go to Item 7.  
If "No," Classify in Class III.

7. IF THERE IS SUFFICIENT INFORMATION TO ESTABLISH SPECIAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II.

- Guidance Document
- Performance Standard(s)
- Device Tracking
- Testing Guidelines
- Other (Specify)

8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD.

- Low Priority \_\_\_\_\_
- Medium Priority \_\_\_\_\_
- High Priority \_\_\_\_\_
- Not Applicable \_\_\_\_\_

9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?

YES  NO  
 NOT Applicable

10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS.

- Low Priority \_\_\_\_\_
- Medium Priority \_\_\_\_\_
- High Priority \_\_\_\_\_
- Not Applicable \_\_\_\_\_

11. IDENTIFY THE NEEDED RESTRICTION(S)

- Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device
- Use only by persons with specific training or experience in its use
- Use only in certain facilities
- Other (Specify)

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Health and Industry Programs (HFZ-215)  
1350 Piccard Drive  
Rockville, MD 20850

**OMB STATEMENT**

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration, (HFZ-215)  
2094 Gaither Road  
Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.*

**Panel Recommendation**

1. GENERIC TYPE OF DEVICE

Air Displacement Plethysmography (BOD POD) Body Composition Analyzer

2. ADVISORY PANEL

Michael Sullivan, VP Operations, Life Measurement

3. IS DEVICE AN IMPLANT (21 CFR 860.3)?

Yes  No

4. INDICATIONS FOR USE IN THE DEVICE'S LABELING

The BOD POD is indicated for measuring body mass and estimating the body composition (i.e., the body fat and lean body mass) of individuals

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General

Device is an active device, so general care of use common with any electrically powered equipment should be taken. Unit is certified to UL 60601-1 and UL 60601-1-2 safety standards. Subject is tested by an operator, who oversees the entire test procedure and can abort the test if necessary. The device is contraindicated for those individuals who are claustrophobic because of the size of the chamber.

RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification Class I Priority (Class II or III Only) N/A

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

N/A

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

1. Device has been utilized in many published studies and trials with no evidence of any safety or effectiveness issues
2. Device has a 10 year track record in the market with no reports of safety incidents or injuries.
3. Device is a Class I device based on criteria on form 3429
4. Device has been determined to be a Class I device by EU Notified Body, for sale in Europe
5. Currently the BOD POD is mis-classified as an impedance plethysmograph - in fact, the BOD POD is an air displacement plethysmograph

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE (e.g., special labeling, banning, or prescription use)

Device is designed to be used by both medical professionals as well as the general population who have reviewed the Operator's Manual and undergone minimal training. Device is contraindicated for subjects who are claustrophobic, and is not designed for use without supervision by test subjects with health conditions that would prevent them from getting the chamber door alone.

10. IF DEVICE IS RECOMMENDED FOR CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

- a. Registration / Device Listing \_\_\_\_\_
- b. Premarket Notification Scalpel used in BiolPod system is already class I device; Unit is low risk from a safety standpoint
- c. Records and Reports \_\_\_\_\_
- d. Good Manufacturing Practice \_\_\_\_\_

11. IF DEVICE IS RECOMMENDED FOR CLASS II, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM PREMARKET NOTIFICATION

- a. Exempt
- b. Not Exempt

N/A

Justifications/Comments

12. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (Components) OR DEVICE MATERIALS (Parts and Accessories)

Device meets UL standards 60601-1 and 60601-1-2 for electrical safety and EMC, respectively

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

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