



Food and Drug Administration Rockville MD 20857

## OCT 2 1 2005

Michael Sullivan
Vice President, Operations
Life Measurement, Inc.
1850 Bates Avenue
Concord, CA 94520

Re: Docket No. 2005P-0207

Dear Mr. Sullivan:

This is an interim response to your petition dated March 21, 2005, which was filed by the Food and Drug Administration (FDA) on May 23, 2005. In your petition, you request that FDA reclassify products "Sonamet Body Composition Analyzer" and "modified Sonamet Body Composition Analyzer" from class II to class I devices. Additionally, you request that these products be given their own product code rather than be included with other body composition analyzers.

Because of the complex issues presented by your petition, we are unable to issue a final response to you at this time. We expect to issue a final response in the near future.

If you have any questions about this interim response, please contact Nancy Stade of our Regulations Staff at (240) 827-0586.

Sincerely yours,

Linda S. Kahan

Deputy Director

Center for Devices and

Sanda S. Kahan

Radiological Health