U.S. Food and Drug Administration

Medical Devices

Abiomed, Inc., AB5000 Circulatory Support System

Recall Class: Class I

Date Recall Initiated: December 16, 2009

Product: Abiomed AB5000 Circulatory Support System

Catalog Number	Serial Numbers
0015-0000	AD5001 through AD5496, except AD5006 and AD5018

These products were manufactured and distributed between May 2003 and December 2009.

Use:

This product supplies power to disposable blood pumps used to support the left and/or right sides of the heart.

Recalling Firm:

Abiomed, Inc.
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Reason for Recall:

The computer may shut down (stop pumping) without an alarm. This defect may cause serious injuries or death.

Public Contact:

Customers may contact the company at 1-800-554-8666.

FDA District: New England

FDA Comments:

At the start of the recall, the company phoned their customers and followed up with a letter dated January 27, 2010. The sales representatives delivered the letter at the time the product repairs were carried out.

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the FDA's MedWatch Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Links on this page:

1. /Safety/MedWatch/default.htm