

ABIOMED INC  
Form 8-K  
November 08, 2006

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934**

**Date of Report: November 8, 2006**

**(Date of earliest event reported)**

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**ABIOMED, Inc.**

**(Exact name of registrant as specified in its charter)**

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**Delaware**  
**(State or other Jurisdiction**

**of Incorporation)**

**04-2743260**  
**(IRS Employer**

**Identification Number)**

**0-20584**

**(Commission File Number)**

**22 Cherry Hill Drive**

**Danvers, MA 01923**

**(Address of Principal Executive Offices, including Zip Code)**

**(978) 777-5410**

**(Registrant's Telephone Number, including Area Code)**

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**Not Applicable**

**(Former Name or Former Address, if Changed Since Last Report)**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- .. Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  
  - .. Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  
  - .. Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  
  - .. Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01 Regulation FD Disclosure**

Abiomed, Inc. currently plans to adopt a 510(k) strategy for the Impella® 2.5 minimally invasive circulatory support system. The Company notes that there are no guarantees that a 510(k) submission will be cleared by the FDA or the timing of such clearance should it occur. If the Company does not obtain 510(k) clearance, its PMA FDA strategy will continue with multiple pivotal centers. The information contained in this report shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Act of 1934, whether made before or after the date hereof and regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Abiomed, Inc.

By: /s/ Daniel J. Sutherby  
Daniel J. Sutherby  
Chief Financial Officer

Date: November 8, 2006