

## **Abiomed CEO Shrugs off Impact of DoJ Probe, FDA Call**

Mass Device

**A U.S. Justice Dept. investigation and the FDA's decision to require pre-market approval for Abiomed's Impella heart pump leave CEO Michael Minogue unfazed.**



Cardiologists aren't paying much attention to the noise around [Abiomed](#) [1] (NSDQ:[ABMD](#) [2]) and its flagship medical device, the Impella heart pump, at least according to chairman, president & CEO Michael Minogue.

That noise centered around a pair of events during the 4th quarter: news of a U.S. Justice Dept. probe into its marketing of the Impella pump and an FDA decision to require the device to undergo a more rigorous approval process.

The Danvers, Mass.-based medical device company [revealed the DoJ probe last year](#) [3], sending share prices down more than 30% in a day. A month later a federal watchdog agency panel [voted to require that the Impella undergo the FDA's pre-market approval protocol](#) [4], which ordinarily requires extensive clinical trials before approval is granted.

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### **Links:**

[1] <http://www.massdevice.com/company/abiomed-inc>

[2] <http://www.google.com/finance?q=abmd>

[3] <http://www.massdevice.com/news/abiomed-plunges-30-federal-investigation-impella-marketing>

[4] <http://www.massdevice.com/news/fda-panel-decision-means-abiomed-will-need-new-pma-impella-pump>