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.

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