Abiomed shares sink as FDA votes to keep Impella pump at highest risk level

Mass Device

The FDA's Circulatory System Devices Panel votes to keep Abiomed's Impella heart pump at a Class III risk level, meaning the devices will continue to pass through the premarket review process.

Abiomed [1] (NSDQ:ABMD [2]) shares slid 7% on Wall Street after the Danvers, Mass.-based cardiac devices maker lost a bid to have its star Impella heart pumps shifted to a lower FDA review risk category.

The FDA's Circulatory System Devices Panel yesterday voted to keep non-roller type cardiopulmonary blood pumps at Class III status, including the Impella, which has U.S. market clearance under the FDA's less stringent 510(k) pathway.

Links:
[1] http://www.massdevice.com/company/abiomed-inc
[2] http://www.google.com/finance?q=abmd