FDA Warns Doc on CoreValve Heart Implant Trial Record-Keeping Issues

Mass Device

A doctor participating in a clinical trial of Medtronic's CoreValve heart implant had "serious violations" of FDA record-keeping rules, prompting a warning letter from the federal watchdog agency.

Hard on the heels of a regulatory win in Europe for one of its heart implants, Medtronic [1] (NYSE:MDT [2]) got some bad news from the FDA regarding another.

Yesterday Fridley, Minn.-based Medtronic won CE Mark approval in the European Union for its next-generation Engager transcatheter aortic valve implant. Today the FDA revealed a warning to a doctor participating in a clinical trial of the medical device company's CoreValve transcatheter aortic valve implant concerning "serious violations" uncovered during inspections last summer.

In a Jan. 14 warning letter sent to Dr. Michael Ring of the Providence Spokane Heart Institute, the federal watchdog agency said inspections in July and August 2012 found "objectionable conditions" at Ring's arm of Medtronic's U.S pivotal trial for the CoreValve device – and violations of his agreement with Medtronic to boot, according to the letter [3].

Links:
[1] http://www.massdevice.com/company/medtronic
[2] http://www.google.com/finance?q=mdt
[3] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm340269.htm