

Abbott failed to reveal pacemaker defect: FDA

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Abbott Labs must be getting a bad case of heartburn after acquiring St. Jude Medical in January.

The Chicago-based medical device company got a warning letter from the Food and Drug Administration this week that detailed years of St. Jude's failures to fix scary — and even deadly — defects in its implantable heart devices.

Among the most egregious examples in the FDA's letter was St. Jude allowing seven patients to receive the company's implantable heart devices in late October — despite the company issuing a recall on the critical gadgets earlier that month due a potentially fatal defect that could cause rapid battery depletion.

To make matters worse, 10 more of the faulty devices — whose defective batteries impaired their ability to deliver life-saving shock therapy — were sent to company field reps after the recall.

Two patients died as a result of premature battery depletion and 10 fainted, St. Jude admitted in October.

Abbott, which acquired St. Jude in January for \$25 billion, said there have been “no complaints of device malfunction” from the seven patients.

But in a letter made public late Wednesday, the FDA found that St. Jude did not disclose one of the deaths in a series of 2014 reports about the risks of premature battery depletions.

In August 2014 St. Jude completed the analysis of the device tied to the patient's death and said the cause of battery depletion “could not be determined.” This was despite St. Jude getting evidence from one of its suppliers of lithium deposits that caused the battery defects, according to the FDA.

Three months later, St. Jude insisted that “there were no serious injury or death directly related to lithium cluster formations.”

Heart patients who have the affected implanted devices were told by St. Jude in October to register for home monitoring with the company's Merlin@Home Monitoring System.

But cybersecurity vulnerabilities of that home-monitoring system were pointed out by a short-seller last August.

St. Jude initially denied claims by Carson Block's Muddy Waters Research that the home monitoring system could be hacked.

But days after being acquired by Abbott in January, St. Jude issued a patch to address the vulnerabilities.

"Abbott either had its eyes wide open in buying these issues at St. Jude, or was negligent in its due diligence," Block said on Twitter Thursday. "Time will tell which was the case."

"We take these matters seriously, continue to make progress on our corrective actions, will closely review FDA's warning letter, and are committed to fully addressing FDA's concerns," Abbott said in a statement Thursday.

Abbott could face an injunction, seizure and monetary penalties from the FDA if it does not correct the violations.

In the meantime, any of Abbott's similar "Class III" life-sustaining implantable devices will not get FDA premarket approval until the issues are corrected.

Abbott shares fell 1.9 percent Thursday, closing at \$42.67.