FDA Warns Of Major Risk With St. Jude Heart Device

The Food and Drug Administration said Wednesday that tool recalled by St. Jude Medical Inc. used to insert heart implants could potentially cause serious injury or death if used in patients.

The company's Amplatzer TorqVue delivery system is used to mend a type of heart defect that causes holes in the upper chambers of the heart. St. Jude recalled all batches and models of the device Jan. 13 after a small number of incidents where the delivery system's wire fractured during surgery.

The devices affected by the recall were manufactured between Aug. 24 and Sept. 24, 2012.

The FDA issued a statement Wednesday that saying it classified the company's action as a Class I recall, meaning patients treated with the devices could be seriously injured or killed.

St. Paul, Minn.-based St. Jude Medical makes a variety of medical devices, including pacemakers and implantable defibrillators, which correct dangerous irregular heartbeats.

The company has struggled in recent years to address quality issues with wires that are used to attach its defibrillators to the heart.

St. Jude stopped selling its Riata wires in late 2010 because of concerns about their insulation, and it recalled the devices in late 2011. Last year the company recalled two other wires, QuickSite and QuickFlex. Around 79,000 Riata leads are implanted in U.S. patients, and the FDA ordered St. Jude to conduct a three-year study to learn more about the risk of insulation failure.

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