

St. Jude Gets EU Approval for Wireless Pacemaker

The Associated Press

St. Jude Medical says it will announce Monday that it received European approval to market the first pacemaker that does not require wires to attach to the heart.

The first-of-a-kind device was developed by California-based startup, Nanostim, with funding from St. Jude. The Minnesota-based device giant also said it would acquire the smaller company for \$123 million, under a previously negotiated option agreement between the two companies.

Pacemakers are battery-powered medical implants that help the heart maintain a steady heartbeat. The devices have traditionally been implanted through a surgical procedure that creates a small pocket in the chest for the device and its wires, called leads, which attach to the heart.

The new Nanostim pacemaker is implanted directly into the heart using catheter-based procedure, which St. Jude says is less intensive than traditional surgery.

The new device is expected to soon launch in some European countries, the company said in a statement.

St. Jude is still conducting studies of the device in the U.S., which are required before seeking approval from the Food and Drug Administration.

St. Jude has been plagued in recent years by recalls of lead wires with its other leading product, defibrillators, which deliver electrical jolts to correct dangerous irregular heartbeats.

The device maker stopped selling its Riata leads in late 2010 because of evidence that the silicone coating on the wires could wear and break down over time, increasing the chance a defibrillator could malfunction and either deliver a shock when none is needed, or fail to shock the patient's heart when it is not beating properly. It recalled the wires in late 2011.

Last November the FDA released an inspection report of the Sylmar, Calif., facility where St. Jude manufactures its defibrillators and other heart devices. The inspectors noted a number of problems with the company's testing procedures, indicating staffers were not following their own quality-control guidelines.

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