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NEWS BRIEF

Guidant Recalls 170,000 Pacemakers

By Peggy Peck, Senior Editor, MedPage Today
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Additional Devices and Vaccines Coverage

INDIANAPOLIS, Sept. 23-Guidant said it is recalling 170,000 of its Insignia and Nexus pacemakers. It was Guidant's fifth recall of pacemakers or implantable cardioverter-defibrillators (ICDs) since June.

In a statement issued Thursday, the company urged patients with Insignia or Nexus pacemakers to consult with their doctors. The company did not suggest across-the-board explants of the devices.

Guidant said the pacemakers were subject to intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, or appearance of a reset warning message upon interrogation.

This latest recall affects roughly 56% of the company's pacemakers. The recall follows a two-week long FDA inspection of Guidant's cardiac unit. The probe focused on the company's Insignia and Nexus lines.

The company says that malfunctions in the pacemakers led to nine emergency hospitalizations but no deaths. "Loss of pacing output associated with these failure modes has resulted in syncope as well as presyncope requiring hospitalization," said Guidant.

The FDA said that failures in the Insignia devices date back to 2003, but the most recent failure occurred in July.

For its part, the company said it has so far confirmed loss of pacing output in 36 of 49,500 Insignia and Nexus pacemakers, including seven that were detected by doctors before being implanted. The failures affected devices shipped before March 2004, which was before a supplier made changes in a timing component, Guidant said.

In addition, the company reported telemetry failures in 16 of 341,000 of the pacemakers.

Guidant also said that it had underestimated the failure rate for two of its ICDs. The actual failure rate for the Contak Renewal and Contak Renewal 2 is 0.7% to 1.8%, which is roughly three times higher than its earlier estimated failure rate. Both devices were included in a Guidant recall issued June 17.

Meanwhile, the Senate Finance Committee notified Guidant that it is investigating whether the company has violated a 2003 agreement that required it to alert the FDA to product problems. The company said it is compliance with the provisions of the agreement.

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