



Guidant recalls heart defibrillators

More than 38,000 implanted devices could malfunction

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INDIANAPOLIS - A company under fire for not telling heart patients about a problem with its implanted defibrillators said Friday that 50,000 of the devices could be flawed and offered to replace more than half of them.

At least two patients with defibrillators made by Guidant Corp. have died, and the company said its devices had failed at least 45 times. Guidant said it was advising physicians about the safety of several models.

Company to replace devices

The Indianapolis-based company said it would replace 28,900 of the implanted defibrillators if requested because the potential flaw couldn't be fixed without removal. More than 20,000 of those are used by patients in the United States.

Another 21,000 devices — 18,000 used by U.S. patients — can be fixed by external reprogramming, the company said.

The U.S. Food and Drug Administration advised patients to talk to their doctors and said it would not recommend whether individual patients with one of the recalled devices should have them removed and replaced. The company said anyone who recently received a defibrillator shock should consult his physician.

An implantable defibrillator, smaller than a pack of cigarettes, is intended to sense an irregular heart rhythm and shock the heart back into correct beating. Vice President Dick Cheney has one made by another company, Minneapolis-based Medtronic.

Patients who are candidates for such defibrillators include those who have had a heart attack or who have had an episode of rapid heart beating or are at risk for that, experts said.

Dr. Kenneth Ellenbogen, professor of medicine at the Virginia Commonwealth University School of Medicine in Richmond, Va., said the best thing for a patient with one of the recalled devices to do is talk to an electrophysiologist, a cardiologist who is a specialist in the field of devices and heart rhythm abnormalities.

7 models recalled

Guidant came under fire this spring after The New York Times reported that it failed to alert physicians about potential problems with the Ventak Prizm 2 DR model defibrillator.

Friday's recall includes that model and the Contak Renewal and Renewal 2; the Ventak Prizm AVT; Vitality AVT; Renewal 3 AVT; and Renewal 4 AVT ICDs. The company said about 63,000 of the devices had been implanted, with nearly 50,000 still in use.

"This is a voluntary recall," U.S. Food and Drug Administration spokeswoman Julie Zawisza said. "We're in complete agreement that they need to do that."

The company said a programming change can be performed for the Prizm AVT, Vitality AVT and Renewal AVT devices at a physician's office to reduce the risk of a short circuit, while defective Prizm 2 DR and Contak Renewal devices will be replaced at no charge.

"Patient safety is paramount and our highest priority," Guidant CEO Ronald W. Dollens said in a statement. "Guidant takes seriously its responsibility to create the most reliable products and services, enhance patient outcome and limit adverse events to patients."

2 deaths reported

The problems with the defibrillators came to light after Joshua Oukrop, a 21-year-old college student from Grand Rapids, Minn., with a genetic heart disease, died in March when his Prizm 2 device short-circuited while he was mountain biking in Utah.

A month later, Guidant notified doctors that a small number of the defibrillators had failed because of an electrical flaw. It also said that it had fixed the flaw in devices made after mid-2002.

A second death, involving a patient with one of the Contak Renewal devices, occurred May 30. Guidant declined to provide any other details Friday. The faulty Contak Renewal defibrillators were manufactured on or before Aug. 26, 2004.

Earlier this month, Guidant stood by its decision to continue selling the Prizm 2 DR for months after a potential flaw prompted a redesign, saying the original device was still reliable.

No failures in the Prizm 2 DR has been reported since April 2002. The faulty Contak Renewal defibrillators were manufactured on or before Aug. 26, 2004, Guidant said.

A Pennsylvania man sued Guidant on June 1, saying the company should have told all patients its devices could short-circuit. Lawyers for 74-year-old John Brennan said they hoped to make the legal complaint into a class-action lawsuit.

Shares of Guidant fell 80 cents, or 1.1 percent, to \$72.86 in afternoon trading on the New York Stock Exchange, where they have traded in a 52-week range of \$49.95 to \$75.15.

Guidant shareholders in April voted overwhelmingly in favor of a planned \$25.4 billion acquisition by Johnson & Johnson. The merger, which still must win regulatory approval in the United States and Europe, would be the largest business deal in the 119-year history of New Brunswick, N.J.-based health care products giant J&J. J&J has said it expects to complete the acquisition during the third quarter.

Johnson & Johnson did not immediately return a message.

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