



**U.S. Food and Drug Administration**



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## **FDA News**

### **FOR IMMEDIATE RELEASE**

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**Media Inquiries:**  
Julie Zawisza, 301-827-6242  
**Consumer Inquiries:**  
888-INFO-FDA

### **FDA Issues Nationwide Notification of Recall of Certain Guidant Implantable Defibrillators and Cardiac Resynchronization Therapy Defibrillators**

FDA is notifying health care providers and patients that the Guidant Corporation is recalling certain of its implantable defibrillators and cardiac resynchronization therapy defibrillators. These devices can develop an internal short circuit without warning, resulting in failure to deliver a shock when needed.

The devices affected by this notification are:

- PRIZM 2 DR, Model 1861, manufactured on or before April 16, 2002
- CONTAK RENEWAL, Model H135, manufactured on or before August 26, 2004
- CONTAK RENEWAL 2, Model H155, manufactured on or before August 26, 2004

The devices are surgically implanted in persons who have a type of heart disease that creates the risk of a life-threatening heart arrhythmia (abnormal rhythm). The devices deliver an electrical shock to the heart to restore normal heart rhythm. The PRIZM 2 and RENEWAL devices are subject to different failures, resulting in the devices' inability to deliver an electrical shock during episodes of arrhythmia -- which could lead to a serious, life-threatening event for a patient. There have been two deaths reported to FDA suspected to be associated with this malfunction.

"FDA's first priority is patient safety," said Daniel Schultz, MD, Director of FDA's Center for Devices and Radiological Health. "We want to ensure that all patients who may be affected by this problem are notified and seek appropriate medical advice from their physicians."

FDA is not making a recommendation on whether individual patients who have one of the Guidant devices should have it removed and replaced. This is a decision that should be made by a patient in consultation with his or her physician, based on the specific medical situation of the patient. Removal and replacement of the device may pose some risk, so it is important that patients and physicians carefully discuss this matter before making a decision.

FDA advises patients to take the following steps:

- If you have not already been notified, contact your doctor to determine if you have an affected PRIZM 2, CONTAK RENEWAL, or CONTAK RENEWAL 2 device.
- Continue to keep your regular doctor appointments.
- If you feel an electrical shock from your device, immediately contact your doctor.
- If there is an audible "beeping" from your CONTAK RENEWAL or RENEWAL 2 device,

immediately contact your doctor or go to the nearest emergency room. Beeping may mean that your defibrillator is damaged.

Guidant also recently informed FDA that it is recalling another set of defibrillator devices called PRIZM AVT, VITALITY AVT, RENEWAL 3 AVT and RENEWAL 4 AVT. The company has said the devices are subject to a memory error, which may affect device performance. Currently, FDA is evaluating this information.

If you are a physician or a patient who has experienced a problem with any of these defibrillators, please send a report to FDA's MedWatch program and to Guidant. See <http://www.fda.gov/medwatch/> for filing information or call 1-800-FDA-1088 (1-800-332-1088).

Guidant will be posting information for physicians on its web site at [www.guidant.com](http://www.guidant.com). If you have further questions, you may contact Guidant at 1-866-GUIDANT (1-866-484-3268).

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[Guidant Safety Advice](#) (June 24, 2005)

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