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Media Inquiries:
Suzanne Treviño, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

FDA Updates Consumers on Guidant Corporation's Implantable Defibrillators

As the Food and Drug Administration (FDA) continues to evaluate the safety and performance of certain implantable defibrillators manufactured by Guidant Corporation, the Agency has now classified the recalled devices. This additional information on the relative health risks of the devices will help patients and doctors take appropriate action, if necessary.

Classifications can fall into three categories, with Class I being the most serious. These numerical classifications are based on the probability that the device failure could lead to adverse health effects.

"Malfunctions in these devices can lead to serious consequences and it's important for patients to call their doctor for additional information and personalized advice," said Daniel Schultz, MD, Director of FDA's Center for Devices and Radiological Health. "However, it's also important to understand that in most cases these defibrillators work well and save lives."

Below is a full list of the 11 devices affected by this recall classification.

PRIZM 2 DR, CONTAK RENEWAL, and CONTAK RENEWAL 2 Devices- Class I

FDA has classified the actions taken by Guidant for some of their defibrillators as Class I recalls. In a Class I recall, there is a reasonable probability that if a particular device is malfunctioning, the malfunctioning device will cause serious adverse health consequences or death.

The firm's investigation determined these devices can develop an internal short circuit when attempting to deliver an electrical shock to the heart, preventing the treatment of abnormal heart rhythms. The problem is caused by deterioration of electrical insulation in the device and can only be detected after the device has already malfunctioned. The device does not give any sign of impending failure and there is no test that predicts whether the device will fail.

Two deaths associated with these 42,000 affected devices worldwide (20,600 are still implanted) have been reported to FDA.

The affected devices 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

A Class I recall designation does not necessarily require removal of the defibrillator. These recalls require Guidant to disclose the device malfunction to patients and doctors while providing additional instructions for safe use of the devices. FDA is not making a recommendation on whether patients who have one of these devices should have it removed and replaced. FDA believes that this decision must be made by the patient in consultation with his or her physician, based on the specific medical situation of the patient. Replacement of the device may pose some risk, so it is important that patients and physicians carefully discuss this matter before making a decision.

Guidant previously informed patients and physicians about the defibrillator problems and has provided additional instructions for safe use of the devices. Guidant's recommendations include:

- If you are not sure which model you have, or if you have other questions regarding your device, you should consult with your physician.
- Continue to keep your normal doctor appointments.
- If you feel a shock, contact your doctor as soon as possible.
- If you or others hear "beeping" from your device, go immediately to your doctor or the emergency room.

VENTAK PRIZM AVT, VITALITY AVT, and RENEWAL AVT Devices- Class II

FDA has classified the previous actions taken by Guidant for these devices as a Class II recall. For a Class II recall, the malfunctioning product may cause temporary or medically reversible adverse health consequences, however the probability of serious adverse health consequences is remote.

These Guidant devices are subject to a memory error which, in rare cases, may limit available therapy. Of the 21,000 devices implanted worldwide (18,000 in the U.S.), two incidents have been confirmed, neither of which resulted in death or injury. The defect can be detected by medical evaluation of the device and Guidant is recommending the device be reprogrammed during the patient's next doctor visit. Guidant is developing an additional non-invasive software solution for this problem, which is expected by the end of the year.

CONTAK RENEWAL 3 and 4, RENEWAL 3 and 4 AVT, and RENEWAL RF Devices- Class II

FDA has classified the previous actions taken by Guidant regarding these devices as a Class II recall.

These devices are subject to a component failure that in rare cases may limit available therapy. A magnetic switch in these devices may become stuck in the closed position, which in some cases inhibits the device's ability to treat ventricular or atrial tachyarrhythmias (abnormally fast heart rhythms) and also accelerates battery depletion. Four occurrences have been confirmed out of approximately 46,000 devices; a fifth occurrence is suspected but cannot be confirmed. In the four confirmed cases, patients and/or physicians were alerted to the condition by audible device tones signaling that the magnetic switch was closed. Based on this information, **it is important that patients who hear tones from their device immediately contact their physician or go to the hospital emergency room.**

As a precautionary measure, Guidant has recommended that physicians discontinue implanting these devices until further notice. For devices already implanted, Guidant has recommended that physicians change "Enable Magnet Use" to "OFF." This will ensure appropriate therapy to treat the patient's abnormally fast heart rhythm.

FDA requests that physicians support Guidant's efforts to acquire additional information about the performance of these devices. Specifically, FDA asks doctors to test these devices at the time they are no longer in service and if possible to return the devices to the manufacturer for analysis.

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

Guidant has posted information for patients and physicians on its web site at http://guidant.com/physician_communications/. If you have further questions, you may contact Guidant at 1-866-GUIDANT (1-866-484-3268).

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Guidant Press Release *(June 24, 2005)*
FDA Press Release *(June 17, 2005)*

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