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**United States Attorney  
District of Minnesota**

*600 United States Courthouse  
300 South Fourth Street  
Minneapolis, MN 55415*

**U.S. Department of Justice  
Office of Consumer Litigation**

*P.O. Box 386  
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## **NOTICE**

### **UNITED STATES OF AMERICA v. GUIDANT LLC**

March 9, 2010

As a claimant in the multidistrict litigation entitled *In re: Guidant Corporation Defibrillators Products Liability Litigation*, MDL Case No. 05-1708, pending in the U.S. District Court for the District of Minnesota, or a person who may have had one of two particular models of implantable cardioverter-defibrillator manufactured by Guidant Corporation (“Guidant”), you are being notified about a pending federal criminal case against Guidant. The case is being prosecuted jointly by the Office of Consumer Litigation of the U.S. Department of Justice (“DOJ”) and the U.S. Attorney’s Office for the District of Minnesota. The prosecutors in this case are DOJ Trial Attorney Ross S. Goldstein and Assistant U.S. Attorney Robert M. Lewis.

Guidant is being charged in the United States District Court for the District of Minnesota with two counts of violating the Federal Food, Drug, and Cosmetic Act with regard to two models of its implantable defibrillators (“ICDs”): (1) the Ventak Prizm 2 DR (Model 1861); and (2) the Contak Renewal 1 (Model H135). The crimes charged involve the events surrounding and leading up to Guidant’s safety advisory and recall of these devices due to electrical short-circuiting on or about June 17, 2005.

Specifically, the United States charges that: (1) in August 2003, Guidant submitted a false and misleading report to the U.S. Food and Drug Administration (“FDA”) regarding the Prizm 2 malfunction; and (2) in March 2005, Guidant failed to notify FDA about a correction it made to the Renewal devices, which Guidant undertook to reduce a risk to health caused by the devices. Both crimes are misdemeanors.

Victims of criminal offenses in federal court are defined as persons who have been “directly and proximately harmed as a result of the commission of a Federal offense.” The Crime Victims’ Rights Act gives crime victims in federal court certain rights:

- The right to be reasonably protected from the accused.
- The right to reasonable, accurate, and timely notice of any public court proceeding, or any parole proceeding, involving the crime or of any release or escape of the accused.
- The right not to be excluded from any such public court proceeding, unless the court, after receiving clear and convincing evidence, determines that testimony by the victim would be materially altered if the victim heard other testimony at that proceeding.
- The right to be reasonably heard at any public proceeding in the district court involving release, plea, sentencing, or any parole proceeding.
- The reasonable right to confer with the attorney for the Government in the case.
- The right to full and timely restitution as provided in law.
- The right to proceedings free from unreasonable delay.
- The right to be treated with fairness and with respect for the victim’s dignity and privacy.

While neither the Department of Justice nor the U.S. Attorney’s Office can act as your attorney or provide you with legal advice, you can seek the advice of an attorney with respect to whether you qualify as a victim of these crimes, the rights described above, or other legal matters. Also, it is important to keep in mind that the defendant is presumed innocent until proven guilty. That presumption requires the court and our offices to take certain steps to ensure that justice is served.

As commonly occurs in criminal cases, the United States has negotiated with Guidant (and its parent company, Boston Scientific Corporation) to enter a guilty plea to these charges. If accepted by the court, Guidant’s entry of a plea of guilty would result in the final resolution of

the case without the necessity of a trial. Any plea agreement between the Government and Guidant must be approved by a judge at a court hearing.

The plea agreement calls for Guidant to plead guilty to these crimes, admit in open court to the facts that form the basis of these charges, and to pay a total criminal penalty (fine and criminal forfeiture) of over \$296 million.

You can monitor the progress of this case, including any scheduled court hearings, by viewing the case-related pages on either of the internet websites established for this case: [www.justice.gov/civil/ocl/cases/Cases/Guidant/index.htm](http://www.justice.gov/civil/ocl/cases/Cases/Guidant/index.htm) or [www.justice.gov/usao/mn/guidant](http://www.justice.gov/usao/mn/guidant). Important case-related documents will be posted on the websites for your review. Please keep in mind that scheduled hearing dates can change on very short notice. If you plan to attend a scheduled hearing, you should frequently view the websites to confirm the hearing date and time.

A corporate representative of Guidant is expected to appear at the U.S. District Court, 316 North Robert Street, in St. Paul, Minnesota on Monday, April 5, 2010, at 2:00 p.m. (Central Time) to be formally advised of the charges against it and to enter its plea. Remember, however, that this date and time could potentially change on short notice. If Guidant enters a guilty plea in accordance with the plea agreement, the court will likely next schedule a sentencing hearing.

Your attendance at the taking of Guidant's plea and the sentencing hearing is not required, but you are welcome to attend either (or both) if you so choose. If you have any questions regarding this matter, please contact one of the following:

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