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Medical Device Manufacturer Guidant Pleads Guilty for Not Reporting Defibrillator Safety Problems to FDA

Company Will Pay Criminal Penalty of More Than $296 Million

WASHINGTON – Guidant LLC pleaded guilty today in St. Paul, Minn., before U.S. District Court Judge Donovan W. Frank to criminal violations of the Federal Food, Drug and Cosmetic Act, the Justice Department announced. The medical device manufacturer's admission of criminal wrongdoing is the result of a four-year investigation into Guidant's handling of short-circuiting failures of three models of its implantable cardioverter defibrillators: the Ventak Prizm 2 DR (Model 1861) and the Contak Renewal (Models H135 and H155). Guidant's Cardiac Rhythm Management division, which produced the defibrillators, is headquartered in Arden Hills, Minnesota.

Implantable cardioverter defibrillators are lifesaving devices used to detect and treat abnormal heart rhythms that can result in sudden cardiac death, one of the leading causes of mortality in the United States. The devices, once surgically implanted, constantly monitor the electrical activity in a patient's heart for deadly electrical rhythms and deliver an electrical shock to the heart in an effort to return the heartbeat to normal. If they fail to operate properly when needed, a person can die within minutes.

Under the terms of the plea agreement with the Justice Department to resolve the charges, which must still be approved by Judge Frank, Guidant pleaded guilty today to withholding information from the U.S. Food and Drug Administration (FDA) regarding catastrophic failures in some of its lifesaving devices. Specifically, Guidant admitted to: (1) making a materially false statement in a required submission to the FDA with regard to the Ventak Prizm 2DR device; and (2) failing to notify the FDA of a "correction" to the Contak Renewal devices, which the company made to reduce a risk to health caused by the devices. As a result of these offenses, the agreement calls for Guidant to pay a combined criminal penalty in excess of $296 million.

"Guidant's guilty plea today is about accountability," said Assistant Attorney General Tony West, who heads the Justice Department's Civil Division. "This successful prosecution serves as an important wake up call to all those who seek to withhold vital information about public health and safety. We will continue our efforts to prosecute those who jeopardize public health by evading their reporting obligations to the FDA."

Guidant, a wholly-owned subsidiary of Boston Scientific Corporation, was charged in federal district court on Feb. 25, 2010. The guilty plea agreement was then filed with the court on March 11, 2010.

"The guilty plea today should serve as a reminder and deterrent to those who would break the laws requiring honesty and cooperation with government regulators whose mission is to protect the health and safety of the public," said Frank J. Magill, Acting U.S. Attorney in this case for the District of Minnesota . "The health care laws are as important as ever. When medical device and pharmaceutical companies fail to live up to their legal obligations, serious criminal consequences will follow."

Today's entry of a guilty plea by Guidant LLC and the proposed resolution would represent the largest criminal penalty ever imposed on a device manufacturer for violating the Food Drug and Cosmetic Act," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. "The FDA will continue to commit enforcement resources to seeking this type of criminal resolution and stiff sanctions when device manufacturers fail to adhere to the statutory and regulatory requirements that exist to ensure the safety and efficacy of their products."

The case was investigated by the FDA's Office of Criminal Investigations and is being prosecuted by AUSA Robert M. Lewis of the U.S. Attorney's Office for the District of Minnesota, and Justice Department Trial Attorneys Ross S. Goldstein and Matthew S. Ebert of the Civil Division's Office of Consumer Litigation. Additional assistance is being provided by Steven Tave of FDA's Office of Chief Counsel.

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