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MEDICAL DEVICE MANUFACTURER GUIDANT CHARGED IN FAILURE TO REPORT DEFIBRILLATOR SAFETY PROBLEMS TO FDA

Boston Scientific Subsidiary Charged with Federal Crimes Related to June 2005 Defibrillator Recalls

WASHINGTON – Medical device manufacturer Guidant LLC, a wholly-owned subsidiary of Boston Scientific Corporation, was charged today with criminal violations of the Federal Food, Drug, and Cosmetic Act related to safety problems with some of its implantable defibrillators. Guidant LLC formerly did business as Guidant Corporation. The Justice Department filed the criminal information today in connection with an agreement with Guidant to resolve the charges. A formal guilty plea agreement is expected to be filed with the court at a later date. Boston Scientific previously announced in a November 2009 press release that the company would pay $296 million on behalf of Guidant in connection with these charges.

According to the information filed today in federal district court in St. Paul, Minn., Guidant concealed information from the U.S. Food and Drug Administration (FDA) regarding catastrophic failures in some of its lifesaving devices. The charges were filed following a four-year investigation into Guidant's handling of short-circuiting failures of three models of implantable cardioverter defibrillators (ICDs): the Ventak Prizm 2 DR (Model 1861) and the Contak Renewal (Models H135 and H155). Guidant issued safety advisories regarding the failures in June 2005.

ICDs 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.

The information alleges that beginning in 2002, Guidant became aware that one of its ICDs, the Ventak Prizm 2 DR, was prone to electrical arcing, rendering the device inoperative and unable to deliver life-saving therapy to the patient in whom it was implanted. Guidant changed the design of the Prizm 2 in November 2002 to correct the problem. The information

charges that in August 2003, Guidant falsely told the FDA that the design changes did not affect the device's safety or effectiveness. In fact, the device changes were made to correct this flaw, according to the information.

In early 2004, Guidant allegedly discovered a similar short-circuiting problem with its Renewal 1 and Renewal 2 devices. Following the July 2004 death of a patient associated with a shorted Renewal in Spain, the information charges that Guidant knew that the physician operating instructions for responding to a short-circuit within the device were false and misleading. In an effort to remedy this, Guidant sent a communication by overnight delivery to physicians which the company dubbed a "Product Update." The information alleges that this communication was actually a correction to the device which attempted to mitigate the safety risk posed by the short-circuiting. Guidant was required by law to alert FDA of this action within ten days. The information charges that Guidant failed to make that notification.

Guidant issued safety advisories on the Prizm 2 and Renewal devices in June 2005. FDA classified those advisories as "Class I" recalls, the most serious classification of recall, concluding that there was a reasonable probability that the affected devices could cause serious adverse health consequences or death.

"The government charges that Guidant committed serious crimes by undermining the FDA's role to guard the American public against potentially dangerous medical devices," said Assistant Attorney General Tony West, who heads the Justice Department's Civil Division. "Our message is clear: We will vigorously prosecute individuals and organizations who put profit over public health and safety by violating the law."

"The community has the right to expect that companies that violate federal law by submitting false or misleading information to the FDA will be held accountable, particularly when that information relates to lifesaving devices, such as defibrillators," said Frank J. Magill, Acting U.S. Attorney for the District of Minnesota on this case. "I want to thank the prosecutors and investigators responsible for this challenging investigation that resulted in these charges being filed. For that, we all can be very thankful."

"This investigation highlights the commitment by FDA's Office of Criminal Investigations to pursue those who seek to circumvent FDA's regulatory authority," said Thomas P. Doyle, Special Agent in Charge of the FDA/OCI Washington Field Office. "The FDA relies on information submitted by regulated entities to fulfill our mission of protecting the public health. Device manufacturers are required to be honest and forthright in all dealings with the FDA, including the submission of post-approval reports and notification of corrective actions.

Guidant put patients at risk by modifying flawed devices without communicating candidly with the FDA and doctors."

The public is reminded that the charges contained in a criminal information are not evidence of guilt. A defendant is presumed innocent unless and until proven guilty. Members of the public, including those individuals who were implanted with one of these devices, may view case-related information including notice of court events and hearings at www.justice.gov/civil/ocl/cases/cases/guidant/index.htm

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 Trial Attorneys Ross S. Goldstein and Matthew S. Ebert of the Department of Justice's Office of Consumer Litigation. Additional assistance is being provided by Steven Tave of FDA's Office of Chief Counsel.

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