
Online supplement: Chronology of the Guidant recalls

Date	Events
February 2002	Guidant Corp. finds flaws in Ventak Prizm 2DR model of implantable cardiac defibrillator (ICD).
Apr. 16, 2002 and Nov. 13 2002	Guidant changes manufacturing of Prizm devices and reports changes to the US Food and Drug Administration (FDA) in its annual report.
Mar. 14, 2005	Joshua Oukrop, 21, recipient of Guidant Ventak Prizm 2 DR 1861 ICD dies. Analysis determines his ICD short-circuited while trying to deliver high-voltage therapy and was permanently disabled.
May 23, 2005	Dr. Beverly Lorell, a Harvard professor and Guidant's vice-president and chief medical and technology officer, sells 22 667 shares of Guidant stock for \$1.68 million. Guidant sends a letter to doctors advising of problems with Prizm 2 DR 1861 (and other ICDs) after being informed by the <i>New York Times</i> of their intention to publish a news article.
May 24, 2005	The <i>New York Times</i> publishes a front-page article about Guidant's failure to disclose problems with ICDs. Guidant Corporation notifies Health Canada of problems with ICDs this date (according to Guidant).
May 25, 2005	Guidant notifies Health Canada of problems with ICDs on this date (according to Health Canada).
June 17, 2005	Health Canada/Guidant Canada send a Dear Doctor letter regarding electrical short circuits in Ventak Prizm 2 DR 1861 ICDs. In the US, Guidant advises physicians of problems with 3 ICD models — Ventak Prizm 2 DR 1861, Contak Renewal and Contak Renewal II — involving 29 000 devices. The US FDA classifies this as a recall. Guidant acknowledges 28 reports of failures worldwide, including 1 death (Oukrop) for Ventak Prizm 2 DR 1861, and 15 failures, including 1 death, involving Contak Renewal and Contak Renewal II devices.
June 20, 2005	Health Canada/Guidant Canada send a second Dear Doctor letter regarding electrical short circuits in Contak Renewal and Contak Renewal 2 ICDs that can lead to device failure. A third Dear Doctor letter advises of problems with Ventak Prizm AVT, Vitality AVT and Contak Renewal AVT ICDs, and a "latching problem" that limits treatment of atrial and ventricular arrhythmias.
July 15, 2005	Guidant Canada tells Health Canada it is recalling certain pacemakers (Pulsar Max, Pulsar, Discovery, Meridian Pulsar Max II, Discovery II, Contak TR pacemakers) because of device failures. There had been 1 nonfatal device failure in Canada. Out of 28 000 devices implanted worldwide, 52 malfunctions had been confirmed.
July 18, 2005	Health Canada/Guidant Canada send another Dear Doctor letter advising of a seal problem that can cause batteries in Pulsar Max, Pulsar, Discovery, Meridian, Pulsar Max II, Discovery II, Virtus Plus II, Intelis II and Contak TR pacemakers to deteriorate and lose pacemaking ability without warning.
July 22, 2005	Health Canada/Guidant Canada send a Dear Doctor letter regarding Ventak Prizm AVT, Vitality AVT and Contak Renewal AVT. This letter revised recommendations in the June 20 letter, one of which could actually increase the possibility of devices failing to detect and treat atrial and ventricular arrhythmias.
Aug. 4, 2005	Health Canada issues a media release advising patients of deterioration of a seal in Guidant's Pulsar Max, Pulsar, Discovery, Meridian, Pulsar Max II, Discovery II and Contak TR pacemakers, which Guidant had told Health Canada about on July 15. The problem may result in batteries deteriorating prematurely and the pacemakers failing to regulate heart rhythm.
Aug. 5, 2005	In response to a <i>New York Times</i> Freedom of Information request, the FDA refuses to release Guidant data (annual reports) regarding previous malfunctions of ICDs, claiming this is a "corporate trade secret."
