EXHIBIT B2

42. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal regulations. *See* 21 U.S.C. § 351(2006).

43. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

44. Manufacturers are required to comply with FDA regulation of medical devices, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360i.

45. Adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 C.F.R. § 803.50.

46. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the

remedial action was reported to the FDA as a removal or correction of the device. *See* 21 C.F.R. § 803.52.

47. Manufacturers must report to the FDA in five business days after becoming aware of any reportable medical device reporting ("MDR"). MDR events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. *See* 21 C.F.R. § 803.53

48. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. § 806.10.

49. Manufacturers must comply with quality system regulations that require manufacturers to meet design-control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming product and take corrective action to prevent recurrence. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See generally* 21 C.F.R. § 820.

50. A manufacturer must report to the FDA through a PMA supplement any new indications for use of a device, labeling changes, or changes in the performance or design

specifications, circuits, components, ingredients, principle of operation, or physical layout of the device. A manufacturer may implement changes to a device that enhance the safety of the device prior to obtaining FDA approval, if the manufacturer submits a special report entitled: "Special PMA Supplement - Changes Being Effected" and provides a full explanation of any labeling changes or changes in quality control or manufacturing process that add a new specification of test method, or otherwise provide additional assurance of purity, strength, or reliability of the device.

51. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." Conditions of Approval at 1, attached to FDA Approval Letter from Daniel G. Schultz, Deputy Director for Clinical Policy, FDA, to Kaye Anderson, Senior U.S. Regulatory Affairs Associate, Guidant Corporation (July 18, 2002); *see* 21 C.F.R. § 814.39.

52. GUIDANT's failure to meet federal regulations applicable to medical devices and GUIDANT's other acts and omissions as described herein directly and proximately caused the Devices to be in violation of federal law and unfit for sale, and proximately caused harm, injury, and deaths to Plaintiffs. Plaintiffs' state law claims are based on parallel state law provisions that do not conflict with federal law.

IV. HISTORY OF THE DEVICES

A. Summary

53. GUIDANT manufactured, promoted, sold, and distributed each of the Devices. At all relevant times, GUIDANT misrepresented the safety of the Devices and negligently manufactured, sold, promoted and distributed them as safe and effective Devices to be used for treatment of individuals with cardiac issues.

54. While GUIDANT was aware that any of the Devices might be subject to certain random and infrequent failures, GUIDANT was also aware of specific, potentially fatal, and nonrandom failures that would occur in the Devices, but failed to disclose any of the subject risks and problems of the devices and failed to take remedial steps to correct them.

55. In March 2005, the death of Joshua Oukrop, whose Ventak Prizm 2 DR 1861 failed, prompted an inquiry first by his physicians. According to a May 24, 2005, New York Times article, the doctors who treated Mr. Oukrop felt that GUIDANT should have notified physicians of the defective nature of the device, since the company "had received enough reports about the flaw to establish a pattern and because high-risk individuals could suffer potentially catastrophic results," such as those that befell Mr. Oukrop. Barry Meier, *Maker of Heart Device Kept Flaw From Doctors*, N.Y. Times, May 24, 2006, at A. Faced with GUIDANT's refusal to disclose to the medical community or the public the potentially fatal defects that their investigation uncovered, Mr. Oukrop's physicians brought the issues to the attention of the New York Times.

56. The New York Times' disclosure that GUIDANT had known of defects in the Ventak Prizm 2 DR 1861 attracted a great deal of attention. As further information was revealed, it became apparent that GUIDANT's CRM Division had known for more than three years that there were defects in the Ventak Prizm 2 DR 1861 and that GUIDANT had been aware of defects in other Devices.

57. Since May 2005, GUIDANT has issued at least 35 notices, in the form of "Dear Doctor" and "Dear Patient" letters, voluntary recalls, and medical advisories relating to the Devices. Even then, some of the advisories and information provided by GUIDANT has been inconsistent, unclear and incomplete. On at least one occasion, a GUIDANT suggestion was subsequently revoked by another GUIDANT advisory. As a consequence, and as described below, today recipients and their medical advisories remain confused and unclear as to the risks of the Devices and the appropriate course of action to take.

58. Certainly, prior to 2005 and despite knowledge of defects in the Devices, GUIDANT failed to communicate information about the defects to the medical community, individuals who had been implanted with the Devices, or the public.

59. While GUIDANT had provided some information to the FDA that information was incomplete and misleading and did not adequately disclose the Device defects. GUIDANT's flawed disclosures did not comply with FDA regulations and violated the

conditions of approval for the Devices.

60. As a result of manufacturing defects, the Devices are unfit for the purpose for which they were sold and do not function as GUIDANT had represented to the FDA, the medical community, and the public. The Devices, in fact, may lead to serious physical trauma and/or death. GUIDANT knew and had reason to know of this tendency for malfunction, device failures, and the resulting risk of injury and death; and yet GUIDANT concealed, omitted, and suppressed this material information, preventing Plaintiffs, the medical community, regulators, and the public from making informed choices about the use of the Devices.

B. Ventak Prizm ICDs

61. GUIDANT designed, manufactured, marketed, promoted, sold, and distributed twelve models of defective pacemaker/defibrillator combinations in the Ventak Prizm line of devices, including the Ventak Prizm 2 VR/DR, Models 1860/1861, Ventak Prizm VR/DR, Models 1850/1851/1855/1856, the Ventak Prizm DR HE, Models 1852/1853, the Ventak Mini IV, Models 1790/1793/1796, and Ventak Mini III HE, Model 1789 (collectively, these are referred to as "Ventak Prizm ICDs").

62. The Ventak Prizm 2 DR 1861 has a potentially fatal defect that can cause short circuiting due to deterioration of a wire insulator within the lead connector block, or header, of the device. The short circuit prevents the Ventak Prizm 2 DR 1861 from providing the necessary and appropriate therapeutic shocks to correct a heart rhythm.

63. GUIDANT first submitted Ventak Prizm for approval in August 1996 pursuant to PMA P960040. The device was originally approved for sale by GUIDANT on July 18, 1997. The original approved device was Ventak Prizm (Models 1810 and 1815). On January 27, 1999, GUIDANT announced the first implantation of the Ventak Prizm.

64. Pursuant to PMA Supplement P960040 S015, GUIDANT sought approval of Ventak Prizm 2 VR/DR (Models 1860 and 1861). GUIDANT received notice of approval of this PMA Supplement in August 2000. GUIDANT began selling the Ventak Prizm 2 DR 1861 in 2000.

65. On July 18, 2002, under supplemental approval, the FDA expanded the approved

indication of all the Ventak Prizm ICDs for the prophylactic treatment of individuals with prior myocardial infarctions and an ejection fraction of 30% or more.

66. According to GUIDANT's May 25, 2005 press release, approximately 24,000 Ventak Prizm 2 DR 1861 ICDs are currently implanted in individuals worldwide. *See* Press Release, Guidant Corp., *Guidant Notifies Physicians Regarding Ventak 1861 Prizm 2 DR Implantable Defibrillator* (May 25, 2005) ("May 25 Guidant Press Release"). GUIDANT later informed the New York Times that as many as 37,000 defective Ventak Prizm 2 DR 1861 devices were implanted. *See* Barry Meier, *Flawed Implants: Disclosure and Delay*, N.Y. Times, June 14, 2005, at C.

67. GUIDANT's Ventak Prizm 2 DR 1861s manufactured are uniformly defective in that they suffer a deterioration of electrical insulation, which will eventually cause the devices to short circuit and fail to function. The malfunction also erases the device's memory, such that a record of the malfunction and any of the patient's previous cardiac arrhythmias is no longer stored in the device, making care provisions for the individuals that much more difficult.

68. At present GUIDANT has not disclosed any test that can predict whether the device will fail, and the device itself gives no warning before or during the malfunction. The defect can be readily detected only in the rare event that the ICD happens to be tested by an electrophysiologist during a short period of time during malfunction. It is not yet clear how often individuals will have to be examined to determine whether their ICD has short circuited and it remains unclear, from what has been made available to the public, as to whether there is an alternative method of identifying a defective device that would minimize the need for ongoing constant examination and medical surveillance. In many cases, the short circuiting erases the device's memory of any adverse event so that the usual telemetric surveillance is not useful.

69. Explantation of the device also has risks, as the ICD is linked directly to the heart, with a lead wire connection placed into the heart tissue. In this situation, scarring occurs easily.

70. In or before February 2002, GUIDANT learned that Ventak Prizm 2 DR 1861s were short circuiting when attempting to build a charge to deliver a therapeutic shock. Specifically, GUIDANT knew that electricity could arc between a lead wire and the backfill tube

in the Ventak Prizm 2 DR 1861.

71. By May or June 2002, GUIDANT's observation of the pattern of short circuiting in the Ventak Prizm 2 DR 1861 was sufficient for a GUIDANT Product Performance Engineer to classify the problem as a "trend" that required further investigation.

72. Meanwhile, by April 2002, GUIDANT had determined that a manufacturing change should be implemented to attempt to adjust the potentially fatal defect in the Ventak Prizm 2 DR 1861. Without FDA approval or any contemporaneous disclosure to the FDA, the medical community, or the public, GUIDANT modified the manufacturing specifications and process of the Ventak Prizm 2 DR 1861 to increase the spacing between the feedthru wire and the backfill tube through injection of additional medical adhesive into the device.

73. In November 2002, once again without FDA approval or any contemporaneous disclosure to the FDA, the medical community, or the public, GUIDANT made further modifications to the manufacturing specifications and process of the Ventak Prizm 2 DR 1961 to thicken the insulation on the backfill tube.

74. Even after April 2002, however, GUIDANT continued to sell the remaining defective ICDs it had in its inventory stock without any disclosure regarding the potentially fatal defect. According to the Independent Panel Report that investigated GUIDANT's practices with respect to reporting device defects, GUIDANT allowed 4,000 such devices to be sold for implant after knowledge of the defect, 1,300 of which GUIDANT shipped after knowledge of the defects. The Independent Panel concluded that, despite knowledge of the defect, GUIDANT made no effort to retrieve defective devices in medical institutions' inventories and that subsequent manufacturing changes were not brought to the attention of physicians or patients.

75. A June 2, 2005 New York Times article revealed that after April 2002, and after GUIDANT had clear and definite knowledge of the defect, nine defective ICDs (manufactured before April 2002 and therefore lacking the modifications intended to increase the spacing between the feedthru wire and the backfill tube) were implanted in individuals at Abbott Northwestern Hospital alone. According to a May 24, 2005 New York Times article, in three cases, the Ventak Prizm devices failed to work when doctors intentionally induced abnormal

heart rhythms during checkups, forcing the doctors to rescue the individuals with external defibrillator paddles of the type used in emergency rooms.

76. In April 2003, GUIDANT closed out the "trend report" on the Ventak Prizm 2 DR 1861, with full knowledge that thousands of those devices that were manufactured before GUIDANT's changes were still implanted and prone to failure.

77. After April 2002, GUIDANT received further information regarding continued failures in the Ventak Prizm 2 DR 1861. For example, GUIDANT received reports of short circuiting in February and July 2004. By February 2005, at least 25 events related to the known problem in the Ventak Prizm 2 DR 1861 had been reported to GUIDANT.

78. On March 14, 2005, a 21-year-old college student from Minnesota with hypertrophic cardiomyopathy collapsed and died of sudden cardiac death when his Ventak Prizm 2 DR 1861 failed due to an electrical short circuit.

79. Physicians at the Minneapolis Heart Institute Foundation explanted the failed device and sent it to GUIDANT for analysis. GUIDANT's analysis confirmed that the device (i) short circuited internally, (ii) had been permanently disabled and (iii) had its memory destroyed. As a result, the device failed to deliver the electric shock necessary to correct the young man's heart rhythm, causing his death.

80. Physicians at the Minneapolis Heart Institute Foundation searched the FDA database for adverse events involving medical devices and identified several other reports involving the Ventak Prizm 2 DR 1861, where the device short circuited and failed in the same manner as their patient's device. They then confronted GUIDANT officials on May 12, 2005 regarding the recurring electrical short-circuiting defect they had discovered in the Ventak Prizm 2 DR 1861 and reminded GUIDANT of its obligations to notify patients and physicians of the defect. GUIDANT officials, however, refused and maintained instead that there was no reason to notify physicians, patients, or the public of the defect in their product.

81. GUIDANT made no public disclosure of the defect in the Ventak Prizm 2 DR 1861 until May 23, 2005, more than three years after GUIDANT learned of the defect, and just hours before the New York Times published an article disclosing the details of the Minnesota

young man's death.

82. While GUIDANT officials took no action to warn the public of the defects in its device prior to May 23, 2005, at least one GUIDANT official did act in the interim to sell company stock. On May 17, 2005, GUIDANT's Chief Medical and Technology Officer sold 23,300 shares of stock in the company for $1.71 million, and on May 23, 2005, the day before the front-page article in the New York Times, she sold another 22,667 shares for $1.68 million.

83. On June 17, 2005, GUIDANT informed physicians in a Dear Doctor letter that it had received twenty-eight reports of the short-circuiting failure in the Ventak Prizm 2 DR 1861s manufactured prior to April of 2002, including one death related to failure of the device, and issued a nationwide notification of recall of the device. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Ventak Prizm® 2 DR, Model 1861 (June 17, 2005) ("June 17 Dear Doctor Letter").

84. In the June 17, 2005 Dear Doctor Letter, GUIDANT described the malfunction as follows: "[D]eterioration in a wire insulator within the lead connector block, in conjunction with other factors, result[s] in an electrical short. The short caused diversion of shock therapy energy away from the heart and into device circuitry. Resultant circuit damages caused permanent loss of shock therapy and pacing." *Id.* at 1.

85. GUIDANT did not file the required PMA Supplement with respect to the 2002 manufacturing changes to the Ventak Prizm 2 DR 1861. Although GUIDANT filed a nonpublic annual report with the FDA in August 2003, GUIDANT's disclosure did not reveal that the Ventak Prizm 2 DR 1861 ICDs might be subject to a potentially fatal failure or that GUIDANT's disclosure was incomplete, misleading, and improper, and was intended to hide the known defect in existing Ventak Prizm 1861s from Plaintiffs and others who were implanted with the device.

86. GUIDANT knew, as well, that the substance used to insulate the wires – polyimide – was prone to failure. GUIDANT became aware that polyimide was specifically prone to cracking which, when combined with exposure to bodily fluids, could lead to potentially fatal short circuiting in the Ventak Prizm 2 DR 1861. Thus, GUIDANT determined that it would replace the polyimide tubing with another substance, PEEK.

87. Finally, after public disclosures of GUIDANT's misconduct, on June or July of 2005, GUIDANT applied for FDA approval to replace polyimide with PEEK in certain devices, such as the Ventak Prizm 2 DR 1861. The FDA approved this change in August 2005 and, in October 2005, described it as "replacing the insulating material on the feedthru wires with a different material that has better degradation properties." FDA, Update of FDA Preliminary Public Health Notification*: Guidant Ventak Prizm 2 DR and Contak Renewal Implantable Cardioverter Defibrillators at 1 (Oct. 13, 2005).

88. In GUIDANT's May 23, 2005, communication with doctors, it did not recommend replacement of the Ventak Prizm devices. *See* May 25, 2005 Guidant Press Release. Moreover, reports suggest that GUIDANT's sales representatives continued to assure physicians that it was unnecessary to replace the defective devices in their individuals.

89. To this day, GUIDANT refuses to suggest replacement of the defective Ventak Prizm 2 DR 1861 devices. Despite patient deaths as a result of the malfunction, and despite GUIDANT's admission that the actual rate of failures may be greater than the reported rate (because deaths associated with device failures may be under-reported because the devices are not routinely evaluated post mortem), GUIDANT told physicians to continue "normal monitoring" and did not encourage them to explant the devices. More recently (and contrary to GUIDANT's original advice to patients and physicians), GUIDANT has recommended that a commanded, or induced, shock may be performed to confirm the integrity of circuitry for individuals implanted with a Ventak Prizm 2 DR 1861, although such testing will not exclude the likelihood the device might later fail because of the defect.

90. Nevertheless, the FDA has classified the actions taken by GUIDANT with regard to the Ventak Prizm 2 DR 1861 devices as Class I recalls, meaning there is "a reasonable probability" that the malfunctioning device "will cause serious adverse health consequences or death." FDA News, FDA Updates Consumers on Guidant Corporation's Implantable Defibrillators (July 1, 2005) ("July 1 FDA Press Release"). The "recalls require GUIDANT to disclose the device malfunction to patients and doctors while providing additional instructions for safe use of the devices." *Id.*

91. As of December 2005, the FDA reported that two deaths had been linked to the Ventak Prizm 2 DR 1861. While GUIDANT reported a predicted occurrence rate of 0.10% to 0.24% in Ventak Prizm DR 1861 devices that were manufactured on or before April 16, 2002, it stated that its computations of potential occurrence rate could be artificially low and that its predictive modeling is "inherently uncertain." GUIDANT also disclosed that a failure had been associated with a Ventak Prizm 2 DR 1861 that was manufactured after April 16, 2002.

92. At all times relevant to this action, GUIDANT knew, and had reason to know, that the Ventak Prizm 2 DR 1861 was not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

C. Contak Renewal 1 and 2

93. GUIDANT manufactured CRT-Ds known as Contak Renewal Model H135 and Contak Renewal 2 Model H155 (hereinafter collectively "Contak Renewal 1 & 2").

94. In or before November 2003, GUIDANT became aware that the Contak Renewal 1 & 2 were prone to short-circuiting problems similar to those found in the Ventak Prizm 2 DR 1861. Like the Ventak Prizm 2 DR 1861, the Contak Renewal 1 & 2 included polyimide tubing.

95. From November 2003 to May 2005, GUIDANT knew of multiple instances in which Contak Renewal 1 & 2 devices had short circuited, including that the short circuiting had resulted in at least one death.

96. While GUIDANT knew that the Contak Renewal 1 & 2 were defective, it failed to disclose the defect to the FDA, the medical community, and the public and continued to sell Contak Renewal 1 & 2 devices with the defect. Not until September 2004 did GUIDANT consider stopping the sale of the defective Contak Renewal 1 & 2 devices, and even then, determined that the GUIDANT sales staff should misrepresent to the medical community the reason for any resulting inventory backorders, in order to avoid questions that could lead to explanation of existing defective devices.

97. In January 2005, GUIDANT considered withdrawing Contak Renewal 1 & 2

devices from the market because of the defects, but concluded that GUIDANT would not disclose the Contak Renewal 1 & 2 defect or withdraw the devices from the market because of the number of defective devices that would be implanted by the time of any such action.

98. On June 17, 2005, only after GUIDANT had been forced to disclose the Ventak Prizm 2 DR 1861 defect and the FDA had initiated a review of GUIDANT's other Devices, did GUIDANT issue a letter to doctors disclosing the defective nature of the Contak Renewal 1 & 2. Specifically, as to these devices, GUIDANT stated that its laboratory analysis had proven that the Contak Renewal 1 & 2 had failed due to "deterioration in a wire insulator within the lead connector block [which,] in conjunction with other factors, could cause a short circuit and loss of device function due to diversion of therapy energy away from the heart and into device circuitry." Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Contak Renewal Model H135 and Contak Renewal 2 Model H155 Devices Manufactured on or Before August 26, 2004 at 1 (June 17, 2005) ("June 17 Contak Renewal 1 & 2 Letter").

99. GUIDANT stated that there is no way of predicting whether "any particular device will fail." *Id.* at 3. According to the June 17 Contak Renewal 1 & 2 Letter, fifteen reports of the malfunction had been confirmed, at least, one of which was fatal, and approximately 16,000 of the devices had been implanted worldwide. *See id.* at 1.

100. Since the June 17 Contak Renewal 1 & 2 Letter, more reports of the malfunction have been confirmed by GUIDANT and at least three more deaths have been associated with the Contak Renewal 1 & 2 defect.

101. GUIDANT further advised physicians to consider performing a commanded shock of the ICD to confirm the integrity of the high-voltage delivery system, and warned physicians that Devices that had failed should be explanted and replaced with new Devices.

102. GUIDANT also stated that, in regard to the Contak Renewal 1 & 2, it had "implemented design and manufacturing corrective actions to address internal shorting within the device header. No devices manufactured after August 26, 2004 have exhibited this failure." *Id.* at 3.

103. Once again, despite the fact that GUIDANT made manufacturing changes on or

around August 26, 2004, which it represented had corrected the defect in the Contak Renewal 1 & 2 devices, GUIDANT failed to inform physicians, patients, and the public until the June 17 Contak Renewal 1 & 2 Letter.

104. In June 2005, GUIDANT recommended that physicians assess whether to replace the Contak Renewal 1 & 2 devices. In September 2005, GUIDANT recommended that physicians reassess device replacement "as a result of the increased projected rate of occurrence." Guidant Corp., Advisory Update: Contak Renewal and Contak Renewal 2, Models H135 and H155 (Sept. 12, 2005).

105. GUIDANT has stated that its estimation of the level of device malfunction in the Contak Renewal 1 & 2 is likely to be understated because the actual number of clinical failures may be greater than the number reported and its predictive modeling is inherently uncertain.

106. The FDA has classified the action taken by GUIDANT with regard to the Contak Renewal 1 & 2 as a Class I recall. The recall requires GUIDANT to disclose the device malfunction to individuals and doctors while providing additional instructions for safe use of the devices.

107. Meanwhile, as with the Ventak Prizm 2 DR 1861, GUIDANT had concluded that the polyimide insulation tubing used in the Contak Renewal 1 & 2 was susceptible to cracking that could result in short circuiting of the device.

108. As with the Ventak Prizm 2 DR 1861, each failure of a Contak Renewal 1 & 2 is potentially fatal.

109. In December 2005, the FDA reported that there had been at least five deaths associated with the defect in the Contak Renewal 1 & 2 and that additional clinical occurrences are likely.

110. At all times relevant to this action, GUIDANT knew, and had reason to know, that the Contak Renewal 1 & 2 were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

D. Contak Renewal 3 and 4

111. GUIDANT also manufactured Contak Renewal 3, Contak Renewal 3 HE, Contak Renewal 4, Contak Renewal 4 HE, Contak Renewal 3 AVT, Contak Renewal 3 AVT HE, Contak Renewal 4 AVT, Contak Renewal 4 AVT HE, Renewal RF, and Renewal RF HE CRT-Ds (hereafter referred to as "Contak Renewal 3 & 4").

112. Long before June 2005, GUIDANT knew that Contak Renewal 3 & 4 were subject to a component failure, in which a magnetic switch can become stuck in the closed position, interfering with the device's ability to treat tachyarrhythmias and depleting the battery. This failure can negatively affect the functioning of the Contak Renewal 3 & 4 devices.

113. GUIDANT has recommended that physicians cease implantation of the Contak Renewal 3 & 4 and use a different product that contains a new switch component. As to currently implanted Contak Renewal 3 & 4 devices, GUIDANT has recommended that individuals seek medical intervention to switch the magnet off and seek immediate medical attention if the device is emitting audible tones. In June 2005, GUIDANT promised, but has not delivered as of it latest Product Performance Report issued in 2006, a programmer software application to correct the problem. The FDA has classified GUIDANT's actions with respect to Contak Renewal 3 & 4 as a Class II recall, which is defined as a product malfunction that may cause temporary or medically reversible adverse heath consequences.

114. At all times relevant to this action, GUIDANT knew, and had reason to know, that the Contak Renewal 3 & 4 were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and potentially catastrophic injuries and deaths.

E. Ventak Prizm AVT, Vitality AVT, and Renewal AVT

115. GUIDANT manufactured potentially defective implantable atrial therapy devices called Ventak Prizm AVT, Vitality AVT and Renewal AVT (collectively referred to as "AVTs"). The Renewal AVT 3 and 4 devices are also subject to the same magnetic switch failure as the Contak Renewal 3 & 4 devices.

116. On or before May 2002, GUIDANT knew that the AVTs were subject to a condition in which a random memory error causes functional "latching" that limits available therapy. A "latched" AVT can also enter a mode of continuous pacing at 120 beats per minute.

117. When an AVT is "latching," it is unable to detect and treat arrhythmias and will fail to recognize and correct a cardiac rhythm that is too fast or irregular, potentially leading to injury or death. Other effects of AVT "latching" include decreased cardiac output, increased myocardial oxygen demand, and excessive wear on the device's battery. If the latching occurs during AVT therapy (i.e., while the AVT is attempting to deliver a shock), continuous shocks could result, regardless of whether they are medically appropriate or necessary. GUIDANT developed and implemented a "fix" to correct the latching in May 2004, but did not disclose to the FDA that the "fix" would be implemented in manufacturing the AVTs until August 2005, after the exposure of the Ventak Prizm 2 DR 1861 defects. Not until June 17, 2005 did GUIDANT notify doctors or the public that device replacement was required if latching occurs and that the issue could be corrected if an implanted AVT – that had not latched – was reprogrammed.

118. On or around July 22, 2005, GUIDANT informed doctors and the public that the programming change recommended in June 2005 could actually cause latching to occur in the AVTs and suggested that a "non-invasive software solution" would be available around September 2005. Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Ventak Prizm AVT, Vitality AVT, and Contak Renewal AVT (July 22, 2005).

119. In January 2006, GUIDANT noted that thirty more failures had been identified, several of which appeared to be related to GUIDANT's improper programming notification. As of April 2006, GUIDANT has not issued the "non-invasive software solution."

120. Individuals implanted with AVT devices must undergo medical monitoring to determine whether their device is functioning properly. In the event GUIDANT issues a "software solution," individuals implanted with AVT devices will require additional medical attention to implement the solution.

121. The FDA originally classified GUIDANT's actions with regard to the AVT

devices as a Class II recall. However, after GUIDANT incorrectly advised the medical community of a programming change that would actually increase the likelihood that latching would occur, the FDA converted GUIDANT's actions with regard to the AVT devices to a Class I recall. According to the FDA, approximately 21,000 of the devices have been implanted worldwide.

122. At all times relevant to this action, GUIDANT knew, and had reason to know, that the AVTs were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

F. Discovery, Pulsar, Meridian, Virtus, and Intelis Pacemakers

123. GUIDANT manufactures a family of pacemakers that includes the Pulsar Max, Pulsar, Discovery, Meridian, Pulsar Max II, Discovery II, Contak TR, Virtus Plus II, and Intelis II devices (hereafter referred to as "Guidant Pacemakers"). As a result of defects in manufacturing, Guidant Pacemakers are subject to degradation of a hermetic sealing component. The result is excessive moisture in the pacemaker case, leading to premature battery depletion and failures to function properly.

124. The failures in the Guidant Pacemakers can occur without warning although, sometimes, a physician can detect a leak-related malfunction before the malfunction causes serious problems.

125. Although GUIDANT knew of the problems with the Guidant Pacemakers as early as 2004, yet again, GUIDANT did not disclose the problems to the FDA, the medical community, or the public until almost two months after the adverse press regarding the hidden defect in the Ventak Prizm 2 DR 1861.

126. GUIDANT first disclosed the problem with degradation of the hermetic sealing component in a letter to doctors on July 18, 2005. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Pulsar Max, Pulsar, Discovery, Meridian, Pulsar Max II, Discovery II, Virtus Plus II, Intelis II, and Contak TR Devices at 1 (July 18, 2005) ("July 18

Dear Doctor Letter"). According to GUIDANT, the leakage into the pacemaker seal can lead to premature battery depletion ("resulting in loss of telemetry and/or loss of pacing output without warning") and inappropriate accelerometer function (resulting in sustained pacing at the maximum rate and lack of appropriate accelerometer rate response during activity). *Id.*

127. The defective Guidant Pacemakers are potentially life-threatening. Loss of pacing output can cause individuals to experience syncope, sometimes requiring hospitalization, and can cause death. Sustained maximum rate pacing has caused heart failure in some individuals implanted with the Guidant Pacemakers, by increasing myocardial oxygen demand. In at least one case, a patient whose device exhibited sustained maximum rate pacing was admitted to the hospital with multiple health issues and subsequently died.

128. According to GUIDANT, testing can determine which devices have already experienced failure, but there is no test to determine if and when devices will fail in the future. GUIDANT estimates that any of the 18,000 Guidant Pacemakers still implanted in residents of the United States may potentially be affected by the hermetic seal degradation defect.

129. In its July 18, 2005 Dear Doctor Letter, GUIDANT advised doctors to consider replacing the affected Guidant Pacemakers in individuals who depend on the device for survival or to prevent serious health consequences. *See id* at 2. According to two cardiologists interviewed for the New York Times, between 20% to 40% of individuals with pacemakers are dependent on their pacemaker for survival. *See* Barry Meier, *Pacemakers By Guidant Have Flaw*, N.Y. Times, July 19, 2005.

130. GUIDANT also advised that individuals should seek attention immediately, "if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have new or increased symptoms of heart failure." July 18 Dear Doctor Letter at 2.

131. The explanation recommended by GUIDANT to address the defects in the Guidant Pacemakers will subject thousands of individuals to explantation surgery and related risks and trauma.

132. GUIDANT has also recommended that individuals implanted with the Guidant Pacemakers consider increasing the frequency of medical visits to increase the likelihood of

detecting a failure that has already occurred.

133. The FDA has classified GUIDANT's action with respect to the Guidant Pacemakers as a Class I recall.

134. Since July 2005, GUIDANT has issued further advisories about potential hermetic seal degradation in the Guidant Pacemakers. Specifically, on January 23, 2006, GUIDANT announced that the Guidant Pacemakers may also be subject to hermetic seal degradation because of a manufacturing error, in which hermetic sealing components susceptible to gradual degradation were mistakenly mixed with a much larger group of non-susceptible components. GUIDANT stated that there is no way to determine which of the 54,000 potentially affected devices might be defective due to the use of improper materials.

135. At all times relevant to this action, GUIDANT knew, and had reason to know, that the Guidant Pacemakers were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in certain individuals, catastrophic injuries and deaths.

G. Insignia and Nexus Pacemakers

136. On or before March 2004, GUIDANT knew that various models in its Insignia and Nexus line of pacemakers ("Insignia & Nexus") are subject to two failure modes.

137. GUIDANT did not disclose the failure modes to the medical community or the public although, by September 1, 2005, GUIDANT had knowledge of at least forty-nine device failures related to the Insignia & Nexus defects.

138. Until the FDA's inspection of GUIDANT's facilities, GUIDANT also failed to fully disclose the Insignia & Nexus defects to the FDA. GUIDANT's disclosure of the Insignia & Nexus device failures was required based on FDA's discovery of the defects and conclusions that GUIDANT had violated numerous federal regulations in manufacturing the Insignia & Nexus devices and in failing to investigate properly and disclose those defects.

139. In the first failure mode, which GUIDANT first disclosed on September 22, 2005, up to 49,500 Insignia & Nexus devices may be subject to failure due to "foreign material within

a crystal timing component." Guidant Corp., Important Medical Device Safety Information & Corrective Action at 1 (Sept. 22, 2005). According to GUIDANT, the foreign material was eliminated in Insignia & Nexus devices shipped after March 12, 2004. *See id.*

140. In the second failure mode, which GUIDANT first disclosed on September 22, 2005, up to 341,000 Insignia & Nexus devices may exhibit a failure of pacing for which GUIDANT could not determine the cause. *See id.* at 2. While GUIDANT asserted that this defect had only been noted at implant, at least one individual had experienced cardiac arrest during attempted implant of a defective Insignia & Nexus device.

141. GUIDANT was unable to identify which Insignia & Nexus devices would fail and suggested medical treatment for individuals feeling short of breath, dizzy, or lightheaded. For the second Insignia & Nexus failure mode, GUIDANT suggested verifying the pacing output of the device before implantation.

142. The FDA has classified GUIDANT's actions with respect to the Insignia & Nexus devices as Class II recalls. A Class II recall is defined as a product malfunction that may cause temporary or medically reversible adverse health consequences.

143. At all times relevant to this action, GUIDANT knew, and had reason to know, that the Insignia & Nexus devices were not safe for the individuals for whom they were prescribed and implanted, because the devices malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, potentially causing catastrophic injuries and deaths.

H. Additional Recent Recalls/Advisories

144. GUIDANT has continued to issue advisories regarding its cardiac Devices. On March 11, 2006, GUIDANT stated that Contak Renewal 3 RF and Contak Renewal 4 RF devices may exhibit a decline in battery voltage related to an unexpected sustained, low level current. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Guidant Renewal 3 RF & Renewal 4 RF (CRT-Ds) at 1 (Mar. 11, 2006). Although GUIDANT claims that the defect can only occur during storage/shipment mode prior to implant, GUIDANT also states that it has confirmed that the internal low level current may occur "transiently" in normal

use post implant. GUIDANT has advised that the FDA may classify this communication regarding the Contak Renewal 3 RF and Contak Renewal 4 RF as a recall.

145. Following the close of the GUIDANT transaction, Boston Scientific initiated a comprehensive product performance review of its CRM products. Boston Scientific announced on May 15, 2006, that it reviewed and assessed the safety and efficacy of its CRM products, as well as the process for determining field communications related to those products. Boston Scientific announced on May 15, 2006 that the product performance review process is ongoing, and the Company plans to continue communicating with physicians regarding future findings.

146. In accordance with the above review, on May 15, 2006, Boston Scientific announced an advisory describing the potential for premature battery depletion identified in certain implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillator (CRT-D) devices. The Company has provided a patient follow-up recommendation as well as a tool to help characterize and predict the potential for early battery depletion on an individual patient basis. No deaths or injuries have been reported in relation to this advisory.

147. In addition, on May 15, 2006, Boston Scientific reported two device malfunctions associated with RENEWAL 3, RENEWAL 4 and VITALITY HE devices whose implantation was subpectoral and reversed from the common positioning. Testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction, if the device is implanted subpectorally. Physicians have been asked to review the specific implant positioning for each patient to determine if any of their patients are affected.

V. GUIDANT'S PAST AND PRESENT ILLEGAL AND REPREHENSIBLE CONDUCT

A. Guidant's Failure To Meet Basic Manufacturing & Regulatory Standards

148. The FDA conducted an inspection of GUIDANT's facilities during the time period of August 22, 2005 to September 1, 2005. At the conclusion of the inspection, the FDA issued a 483 Inspection Report ("FDA 483"), in which it detailed violations of federal regulations by GUIDANT. *See* FDA 483 Inspection Report (Sept. 1, 2005) ("Sept. 1 FDA

483").

149. The stated purpose of the FDA 483 is "to assist the firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration." FDA 483 Inspection Report at 2 (Feb. 8, 2006) ("Feb. 8 FDA 483").

150. Included in the Sept. 1 FDA 483 for GUIDANT were the following fifteen observations of violations noted by FDA:

- procedures for conducting quality audits were incomplete;
- "[n]ot all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified;"
- procedures were not completed and implemented for monitoring and controlling of process parameters for validated processes;
- "[a] process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures;"
- "[p]rocedures to ensure that equipment is routinely maintained were not established;"
- "[d]uring production, component and device characteristics are not fully monitored and controlled;"
- "[p]rocedures for changes to methods were not complete;"
- management with executive responsibility has not ensured that an adequate and effective quality system has been implemented and maintained at all levels of the organization;
- "[s]oftware used as part of production and the quality system has not been fully validated for its intended use according to an established protocol," and electronic records which are used do not have requirements to ensure that they are trustworthy, reliable, and generally equivalent to paper records;
- "appropriate sources of quality data are not adequately analyzed to identify existing and potential causes of nonconforming product and other quality problems;"

- processes have not been approved and electronic records do not meet employee accountability/responsibility policy and signature manifestation requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records;
- "[t]he document control procedures do not designate an individual to review documents for adequacy and approve them prior to issuance;"
- "[r]ework and reevaluation activities have not been documented in the device history records;"
- "[d]ocument control procedures are not complete;" and
- the device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Feb. 8 FDA 483 at 1-6.

151. The findings of the FDA inspection of August and September 2005 confirm that GUIDANT was violating federal and state law in manufacturing the Devices.

152. From December 2005 to February 2006, the FDA again inspected GUIDANT's manufacturing facilities and found further egregious violations of basic manufacturing standards fundamental to federal and state law. *See* Feb. 8 FDA 483. Specifically, the FDA found that GUIDANT had failed to disclose the AVT device defects that it had known about since May 2002 and had attempted to correct through revised software implemented by May 2004. *See id.*

153. The FDA's inspections led to recalls of GUIDANT Devices at issue in this litigation and specifically criticized GUIDANT's manufacturing and disclosure processes, stating that GUIDANT had failed to establish adequate procedures in violation of federal regulations.

154. Moreover, with respect to each of the GUIDANT Devices at issue in this litigation, Defendants failed to comply with FDA regulations and the Conditions of Approval relating to relevant PMA and PMA Supplements.

155. The claims alleged herein set forth sufficient facts to establish manufacturing defects with respect to the GUIDANT Devices.

156. No claims alleged herein are preempted under any provisions of the Medical Device Act or FDA regulations.

157. GUIDANT's failure to meet federal regulations applicable to medical devices and GUIDANT's other acts and omissions as described herein directly and proximately caused the Devices to be in violation of federal and state law, and proximately caused harm and injury to Plaintiffs.

B. Guidant's Concealment of the Device Defects

158. GUIDANT's failure to disclose accurately and adequately the known defects in the Devices and concealment of known defects from the FDA, the medical community, and from Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

159. No Plaintiff could have discovered the existence of the short-circuit defect in the Ventak Prizm 2DR 1861, until at least after June 17, 2005, when that the public was officially notified by the FDA that GUIDANT was voluntarily withdrawing the Ventak Prizm 2 DR 1861 from the market.

160. It was not until June 17, 2005, that the public was officially notified by the FDA that the agency was recalling Contak Renewal 1 & 2 devices. At no point prior to June 17, 2005, did GUIDANT notify any Plaintiff, the medical community, or the public that the Contak Renewal 1 & 2 were defective.

161. It was not until June 17, 2005, that the public was notified by the FDA that AVTs were defective and were resulting in memory failures. At no point prior to June 17, 2005, did GUIDANT notify any Plaintiff, the medical community, or the public that the AVTs were defective.

162. It was not until July 2005 that the public was officially notified that SOME OF the Guidant Pacemakers were defective. At no point prior to July 22, 2005 did GUIDANT notify any Plaintiff, the medical community, the FDA, or the public that the Guidant Pacemakers were defective.

163. Meanwhile, although GUIDANT regularly issued Product Performance Reports purporting to disclose information regarding the Devices, it was not until late 2005 that such

Product Performance Reports included any information from which a reader could discern that GUIDANT was aware of potentially life-threatening malfunctions that could occur in the Devices.

164. GUIDANT's failure to properly disclose the known defects in the Devices and their active concealment of the known defects from the FDA, the medical community, and Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

165. GUIDANT is estopped from relying on the statute of limitations defense because it actively concealed the ICD defects by suppressing reports, failing to follow through on FDA notification regulations, and failing to disclose known defects to the medical community, the public, or the Plaintiffs. Instead of revealing the defects, GUIDANT continued to represent the Devices as safe for their intended use.

166. GUIDANT's conduct, as described in the preceding paragraphs, amounts to conduct that GUIDANT must have realized was dangerous, heedless and reckless, without regard to the consequences or to the rights and safety of Plaintiffs.

167. At all times relevant to this action, GUIDANT knew, and had reason to know, that the Devices were not safe for the individuals for whom they were prescribed and implanted, because the Devices short circuited and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some individuals, catastrophic injuries and deaths.

168. As a result of defects in both the design and the manufacture of the Devices, GUIDANT knew and had reason to know that the Devices would fail to function properly, and have a significantly decreased life expectancy – which was concealed from the FDA, the medical community, and the individuals in whom the Devices were implanted.

169. Further, GUIDANT knew and had reason to know that the life expectancy of the Devices was significantly shorter than that which GUIDANT represented to the FDA, the medical community, and those in whom the Devices were implanted. GUIDANT affirmatively concealed and suppressed the true information about the life expectancy and reliability of the Devices.

170. At all times relevant to this action, GUIDANT knew, and had reason to know, that the Ventak Prizm 2 DR 1861 and Contak Renewal 1 & 2 were not safe and effective for the individuals for whom they were prescribed and implanted, because after short circuiting the Devices could fail to function and the internal memory within the Devices would be erased, thereby concealing both evidence of the short circuit and any medical memory of the patient's arrhythmias in the period preceding the short-circuiting episode. This malfunction prevents the doctor from properly reviewing the patient's heart rhythm history, and from providing related medical services, such as possibly adjusting necessary medication. Further, while GUIDANT has recommended that doctors consider inducing shocks to their patients to determine if the devices are already malfunctioning, it is otherwise impossible for doctors to test these devices to determine whether they will short circuit and fail to perform as intended.

171. Nonetheless, in its June 24, 2005 letter to patients, GUIDANT continued to falsely reassure the public that "[t]he safety and well being of patients is foremost in our minds" and that GUIDANT maintains a "steadfast dedication to patients." Letter from Allan Gorsett, Vice President, Reliability and Quality Assurance, Guidant Corp., to Patients with Contak Renewal 1 & 2 Devices at 1 (June 24, 2005).

C. Guidant's Deceptive Promotional and Marketing Activities

172. Consistent with their failure to disclose defects and its other concealments of the defects in the Devices, throughout the years that it was manufacturing and selling the Devices, Defendants' promotional, marketing, and advertising materials consistently concealed the defects about which it knew or should have known, as set forth at length above. Routinely, the information provided in those materials was materially misleading and incomplete. While otherwise affirming aspects of the Devices, the defects and complications associated with the devices were consistently never disclosed. By way of another example, in marketing brochures, GUIDANT affirmatively and specifically touted the longevity of its ICDs and pacemakers again without disclosing its defects and complications.

173. In reality, Defendants' devices did not have such longevity and by virtue of the defects inherent in the products, Plaintiffs and many other individuals have had to have their

devices prematurely explanted long before the expected life of the products had run.

D. Guidant's Continued Failure To Provide Adequate and Accurate Information

174. Tens of thousands of individuals' lives, including Plaintiffs herein, rely upon the proper functioning of their ICD and pacemakers, and they – along with their physicians – have been vigorously attempting to assess the risks that they now face.

175. Yet, due to GUIDANT's delayed disclosure and shifting positions, individuals and physicians remain uninformed and confused about whether the Devices should be explanted, or whether all of the defects have been disclosed.

176. GUIDANT sales representatives consistently visit with individuals and physicians, attempting to persuade them that, notwithstanding the various FDA Class I recalls, explantation of the Devices is unnecessary.

177. It remains unclear how many individuals are affected by the defective Devices, although based on the population of GUIDANT individuals whose claims are asserted in this and other federal complaints, it is likely to be at least 80,000 individuals in the United States. Although GUIDANT should have records regarding the Devices, information on the number of affected individuals from GUIDANT is variable and confusing:

178. GUIDANT originally reported that some 24,000 currently-implanted Ventak Prizm 2 DR 1861 devices worldwide were at risk of failure. *See* May 25 Guidant Press Release.

179. GUIDANT later informed the New York Times that the total number of Ventak Prizm 2 DR 1861 devices implanted with the defective design was 37,000. *See Flawed Implants: Disclosure and Delay.*

180. According to the June 17, 2005 Dear Doctor Letter, an additional 20,950 devices were subject to failure. *See* June 17 Dear Doctor Letter at 1.

181. In a June 23, 2005 letter to physicians, GUIDANT reported that a further additional 46,000 devices were subject to failure. *See* Guidant Corp., Urgent Medical Device Safety Information & Corrective Action: Contak Renewal 3 and 4, Renewal 3 and 4 AVT, Renewal RF at 1 (June 23, 2005).

182. FDA estimates have put the total number of potentially affected Devices at

87,600, including 20,600 Devices with deteriorated electrical insulation (such as the Ventak Prizm 2 DR 1861); 21,000 Devices with the "latching" error (such as the AVTs); and 46,000 Devices with the malfunctioning magnetic switch (such as the Contak Renewal 3 & 4).

183. Information on what individuals implanted with one of the Devices should do is similarly confusing. For example, in June 2005, GUIDANT stated that it "does not recommend routinely using a commanded shock to detect the shorting problem" in the Ventak Prizm 2 DR 1861. June 17 Dear Doctor Letter at 2. In December 2005, GUIDANT notified physicians that they "may choose to perform a commanded shock to confirm integrity of the high voltage delivery circuit." Advisory Update: Ventak Prizm 2 DR Model 1861 (Dec. 20, 2005).

E. Guidant's History of Criminal Misconduct

184. In June 2003, GUIDANT's then wholly-owned subsidiary, Endovascular Technologies, Inc. ("EVT"), agreed to plead guilty to nine felony counts of introducing misbranded medical devices into interstate commerce, in violation of 21 U.S.C. § 331(a), and one felony count of making false statements to the FDA, as well as the payment of $92.4 million to settle the charges. The plea agreement related to a medical device known as the Ancure Endograft System, which was released in September 1999, withdrawn in March 2001, released again in August 2001, and finally withdrawn in March 2003. The device was used to treat abdominal aortic aneurysms, a potentially life-threatening condition. GUIDANT's EVT subsidiary became aware of serious and sometimes fatal malfunctions in the device's delivery system, yet concealed information about the malfunctions from the FDA, physicians, and the public. At least seventy-six deaths and dozens of invasive surgeries resulted from the malfunctions.

185. The FDA sought criminal punishment and civil fines for GUIDANT's failure to uphold its "serious responsibility to report deaths and injuries associated with [its] products to the FDA." *See* http://www.fda.gov/fdac/departs/2003/603_irs.html (reflecting information originally published in FDA Consumer Magazine Volume 37, Number 6 | November-December 2003). The settlement required GUIDANT to enter into a Corporate Integrity Agreement with the Office of the Inspector General of the Department of Health and Human Services,

GUIDANT's violation of which is the subject of the current FDA inquiry.

186. The Corporate Integrity Agreement required GUIDANT to develop and maintain practices and procedures to assure its compliance with federal law, including compliance with the MDR procedures set forth in 21 C.F.R. § 803, the failure analysis and quality assurance procedures set forth in 21 C.F.R. § 820, and the recall and notification procedures set forth in 21 C.F.R. § 806. The Corporate Integrity Agreement also required GUIDANT to develop and maintain practices and procedures to comply with 21 C.F.R. § 814 concerning device modifications, instructions for use, pre-market approval conditions and to comply with 21 C.F.R. §§ 803, 806 and 820, concerning maintaining MDRs, implementing device Removals and Corrections, and establishing Quality Systems. The Corporate Integrity Agreement also specified that GUIDANT must comply with the federal regulations for reporting adverse events, or MDRs, in accordance with 21 U.S.C. § 360i.

187. Despite the obligations described above in the Corporate Integrity Agreement executed by GUIDANT on June 30, 2003, GUIDANT failed to satisfy those obligations in its manufacture and sale of the Devices.

188. For example, as to the Devices, GUIDANT failed to timely report adverse events; failed to timely conduct failure investigations and analysis; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

189. Moreover, as the Independent Panel concluded, GUIDANT's policies and practices with respect to internal communications and review of device defects were seriously lacking in several regards, in a manner wholly inconsistent with GUIDANT's duties under the Corporate Integrity Agreement to maintain policies and procedures that ensure compliance with federal device safety regulations. As one example, the Independent Panel concluded that GUIDANT did not have uniform corporate wide practices for quality control, corrective action, risk assessment, risk management, and public communications.

190. According to a June 16, 2005, Minneapolis newspaper article, federal regulators have begun an inquiry into whether GUIDANT has violated the Corporate Integrity Agreement, signed by its wholly-owned subsidiary in 2003, in the wake of civil and criminal charges related to a different malfunctioning medical device and GUIDANT's attendant attempt to cover up the incidents of malfunction. *See* Janet Moore, *Federal Inquiry Looks at Guidant Case*, Star-Tribune, June 16, 2005.

191. GUIDANT clearly has a history of withholding information from the FDA, the medical community and its customers, and has previously pleaded guilty to criminal and civil charges for failing to provide accurate data about other defective products. GUIDANT's conduct shows a reckless disregard for public health and the safety of its customers. In the context of its past criminal history and its recent violation of the Corporate Integrity Agreement, GUIDANT's conduct in this situation has been particularly egregious. For this and other reasons, Plaintiffs submit that punitive damages claims, raised when and as appropriate under governing law, will prove to be warranted in this case.

F. An Independent Expert Panel Hired By Guidant Found Many Of Its Processes To Be Flawed, Specifically As It Pertains To Guidant's Failure To Disclose The Risks, Complications And Defects Associated With Its Devices.

192. In the summer of 2005, GUIDANT CORPORATION established an Independent Panel of experts to recommend guidelines for surveillance and assessment of malfunctions of its implantable defibrillators and pacemakers, and how and when to communicate safety-related information to physicians and patients. On or about March 20, 2006, the Independent Panel issued its Report, which outlined, among other things, a "...series of problems requiring attention." The Report, in part, noted the following problems:

a. "Neither the CRM business nor GUIDANT CORPORATION has in place a process for comprehensive internal ... or external ... medical review of the clinical impact of product malfunction." (CRM (Cardiac Rhythm Management) is a business unit of GUIDANT CORPORATION that manufactures implantable pacemakers and defibrillators.) Report, p. 46.

b. "The Product Performance Engineer positions (at CRM) have been chronically understaffed." Report, p. 54. (Product Performance Engineers are responsible for

evaluating and classifying device complaints, as well as integrating hardware findings generated by a reliability engineer, and consult with others as needed to determine the relevance of the problem.) Report, p. 12.

c. "Individuals with medical training are not sufficiently involved in the CAPA (Corrective and Preventative Action) process." Report, p. 55. (CAPA is defendants' postmarket product performance evaluation system for their implantable cardiac devices.) Report, p. 52.

d. "The method for long-term tracking of events with potentially serious patient outcomes is inadequate." Report, p. 55.

e. "[T]here is no metric or presentation that permits a comparison for a single specific life-threatening trend over time, irrespective of whether the overall failure rate of the device meets design expectations." Report, p. 55.

f. "There is insufficient attention paid to uncertainties." Report, p. 55.

g. "Medical oversight by physicians with clinical experience appears to be a secondary priority." Report, p. 67.

h. "There are no (medical) advisory boards that serve primarily as advocates for quality and patient safety." Report, p. 74.

i. "CRM ...did not provide effective physician oversight of decisions that affected the safety of patients who receive (its) products." Report, p. 75.

j. "(CRM's approach for management of safety information) ...runs contrary to the policy that patient safety is the first priority for evaluation, and managing device malfunction." Report, p. 80.

k. "At the corporate level, Guidant has not paid adequate attention to the challenges associated with communicating the risks that evolved in the CRM business, however small, to patients, family members, and physicians. In part, this appears to result from the absence of corporate oversight of the CRM business generally...." Report, p. 81.

193. As outlined above, the Independent Panel hired by GUIDANT found multiple problems with GUIDANT's quality control processes – particularly with respect to post-market

evaluation of the Devices – which are not consistent with appropriate concern for patients and quality.

G. The Guidant Co-Defendants Are Agents and Alter Egos of One Another

194. At all times herein mentioned, each of the GUIDANT DEFENDANTS was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other GUIDANT DEFENDANTS herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other GUIDANT DEFENDANTS, knowing that their collective conduct constituted a breach of duty owed to Plaintiffs.

195. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the GUIDANT DEFENDANTS such that any individuality and separateness between them has ceased and all the GUIDANT DEFENDANTS are the alter ego of the other GUIDANT DEFENDANTS and exerted control over those Defendants. Adherence to the fiction of the separate existence of the GUIDANT DEFENDANTS as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

196. At all times herein mentioned, the GUIDANT DEFENDANTS together, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiffs. As such, each Defendant is individually, and jointly and/or severally, liable to Plaintiffs for Plaintiffs' damages.

197. The GUIDANT DEFENDANTS acted jointly in the concerted tortuous conduct alleged herein.

198. At all times herein mentioned, the officers and/or directors of the GUIDANT DEFENDANTS named herein participated in, authorized and/or directed the production and promotion of the aforementioned Devices when they knew, or with the exercise of reasonable

care and diligence should have known, of the hazards and dangerous propensities of said Devices, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiffs.

199. Boston Scientific, by acquiring the GUIDANT DEFENDANTS, apparently with full knowledge of their actions, has assumed the liabilities of the GUIDANT DEFENDANTS.

FIRST CAUSE OF ACTION
(STRICT LIABILITY – FAILURE TO WARN Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC and DOES 1 through 100, inclusive)

200. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

201. At all times herein mentioned, GUIDANT DEFENDANTS developed, designed, researched, manufactured, assembled, distributed, promoted, supplied, sold and/or otherwise introduced into the "chain of commerce" the devices implanted in Plaintiffs, hereinafter the subject devices.

202. At all material times, the subject device implanted into Plaintiff CLIFFORD HOSLER on April 29, 2002 and the subject device implanted into Plaintiff DALE PATTON on September 27, 2002 that were designed, manufactured, assembled, distributed, promoted, sold and supplied by GUIDANT DEFENDANTS, were defective due to inadequate warning or instruction in that GUIDANT DEFENDANTS failed to conform with federal requirements and GUIDANT DEFENDANTS knew or should have known that the products created significant risks of serious bodily harm and/or death to consumers and GUIDANT DEFENDANTS failed to use reasonable care to warn, give adequate warning or provide facts describing the dangerous propensities of the products to consumers, their physicians, and those whom GUIDANT DEFENDANTS could expect to use the products or be endangered by the products' probable use. GUIDANT DEFENDANTS, knowing that their products could cause serious injury and/or death, continued to aggressively market, promote, distribute, and sell the dangerously defective products.

203. Absent proper and adequate warning and instruction by GUIDANT

DEFENDANTS, ordinary consumers, such as Plaintiffs, would not have recognized the risks of the subject devices, as described herein, and Plaintiffs did not recognize such risks.

204. The first time GUIDANT DEFENDANTS advised the consuming public, including Plaintiffs, of the problems with the subject devices was between June 17, 2005 and May 15, 2006, as outlined above. The reason GUIDANT DEFENDANTS acted in the manner referenced above was for their collective personal, professional and financial enhancement.

205. Because information concerning the inherently dangerous characteristics of the subject device was unknown to and concealed from the general public, including Plaintiffs and Plaintiffs' physicians, GUIDANT DEFENDANTS were under a duty, yet intentionally failed to disclose to patients, the consuming public, and the medical community that their products were defective, unsafe, and inherently dangerous for their intended use by consumers such as Plaintiffs.

206. The subject devices surgically implanted in Plaintiffs were used in a way that was reasonably foreseeable to GUIDANT DEFENDANTS, and were in substantially the same condition as when it left possession of GUIDANT DEFENDANTS.

207. As a direct and proximate result of the aforesaid tortious conduct of GUIDANT DEFENDANTS, and as a direct and legal result of the negligence, carelessness, and other wrongdoing, actions and omissions of GUIDANT DEFENDANTS, as described herein, Plaintiffs suffered injuries and damages as alleged herein.

208. As a direct and proximate result of the acts, omissions, negligence, carelessness, and wrongful and tortious conduct of the defendants, as described herein, Plaintiffs have and may sustain serious, severe and permanent personal injuries and damages; serious and severe emotional distress; severe distress about present and future injuries from the defective devices, the explant surgeries, the fact that Plaintiffs can only have so many replacement surgeries, and the risk of further thrombosis, heart attacks, strokes, and/or further complications.

209. As a direct and proximate result of the acts, omissions, negligence, carelessness, and wrongful and tortious conduct of the defendants, as described herein, Plaintiffs were compelled to and did employ the services of hospitals, physicians, surgeons, nurses, and the like

to care for and treat Plaintiffs and Plaintiffs did incur hospital, medical, professional and incidental expenses. Plaintiffs are informed and believe and therein allege that Plaintiffs will unnecessarily, by reason of Plaintiffs' injuries, incur additional like expenses for an indefinite period of time in the future.

210. As a direct and proximate result of the acts, omissions, negligence, carelessness, and wrongful and tortious conduct of the defendants, as described herein, Plaintiffs have been prevented from attending to their usual occupations, thereby sustaining loss of income, the duration and extent of which is yet undetermined, and Plaintiffs are informed and believe and upon such information and belief allege that Plaintiffs will be prevented from attending to said usual occupations for an indefinite period of time in the future and will incur an additional loss of income; and Plaintiffs have sustained a loss of earning capacity.

211. Plaintiffs are informed and believe and based upon such information and beliefs allege that Plaintiffs' injuries will likely result in some permanent disability, all to Plaintiffs' detriment in a sum according to proof.

212. All of the foregoing injuries and damages have substantially reduced Plaintiffs' ability to enjoy life, and have caused and continue to cause Plaintiffs great mental, physical and nervous pain and suffering.

213. The damage amounts sought to be recovered by Plaintiffs, and each of them, are well in excess of the jurisdictional minimum for this Court.

214. The aforementioned acts of GUIDANT DEFENDANTS, which were performed, authorized and/or ratified by GUIDANT DEFENDANTS' officers, directors and/or managing agents, were willful, wanton, malicious, fraudulent, and oppressive, as defined by *California Civil Code* § 3294, and evidences a flagrant disregard for human life, therefore justifying an award of exemplary and punitive damages.

SECOND CAUSE OF ACTION

(STRICT LIABILITY – DESIGN DEFECT Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC and DOES 1 through 100, inclusive)

215. Plaintiffs incorporate by reference each and every allegation within the preceding

paragraphs as though fully set forth herein.

216. The subject device implanted into Plaintiff CLIFFORD HOSLER on April 9, 2002 and the subject device implanted into Plaintiff DALE PATTON on September 27, 2002 as designed by GUIDANT DEFENDANTS were defective.

217. GUIDANT DEFENDANTS knew or should have known that the design of the subject devices was more dangerous than an ordinary consumer would expect when the products were used in an intended or reasonably foreseeable manner.

218. The subject devices implanted in Plaintiffs were in substantially the same condition as when they left possession of GUIDANT DEFENDANTS.

219. Any changes made to the product by Plaintiffs' physicians, if any, after the products left the GUIDANT DEFENDANTS' possession were reasonably foreseeable to GUIDANT DEFENDANTS.

220. The subject devices as designed by GUIDANT DEFENDANTS were defective in that when the products left the hands of GUIDANT DEFENDANTS, they did not conform to federal requirements, the foreseeable risks of the products exceeded the benefits associated with their design, and they were more dangerous than ordinary consumers, such as Plaintiffs, would expect.

221. As a direct and proximate result of the aforesaid tortious conduct of GUIDANT DEFENDANTS, and as a direct and legal result of the negligence, carelessness, and other wrongdoing, actions and omissions of GUIDANT DEFENDANTS, as described herein, Plaintiffs suffered injuries and damages as alleged herein.

222. The aforementioned acts of GUIDANT DEFENDANTS, which were performed, authorized and/or ratified by GUIDANT DEFENDANTS' officers, directors and/or managing agents, were willful, wanton, malicious fraudulent, and oppressive, as defined by California Civil Code Section 3294, and evidence a flagrant disregard for human life, therefore justifying an award of exemplary and punitive damages.

///

///

THIRD CAUSE OF ACTION
(STRICT LIABILITY – MANUFACTURING DEFECT Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., and DOES 1 through 100, inclusive)

223. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

224. The subject devices placed into the stream of commerce by GUIDANT DEFENDANTS, were defective in their manufacture and construction when they left GUIDANT DEFENDANTS' possession in that they deviated from product specifications, failed to comply with federal requirements, and posed serious and unreasonable risks of injury and death to foreseeable consumers, such as Plaintiffs, when used in an intended or reasonably foreseeable manner.

225. As a direct and proximate result of the aforesaid tortious conduct of GUIDANT DEFENDANTS, and as a direct and legal result of the negligence, carelessness, and other wrongdoing, actions, and omissions of GUIDANT DEFENDANTS, as described herein, Plaintiffs suffered injuries and damages as alleged herein.

226. The aforementioned acts of GUIDANT DEFENDANTS, which were performed, authorized and/or ratified by GUIDANT DEFENDANTS' officers, directors and/or managing agents were willful, wanton, malicious fraudulent, and oppressive, as defined by California Civil Code Section 3294, and evidence a flagrant disregard for human life, therefore justifying an award of exemplary and punitive damages.

FOURTH CAUSE OF ACTION
(NEGLIGENCE Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC, SUTTER SOLANO MEDICAL CENTER, NORTHBAY HEALTHCARE CORPORATION, and DOES 1 through 100, inclusive)

227. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

228. At all material times, the defendants had a duty to provide adequate warnings regarding the use of and to exercise reasonable care in all aspects of the designing, testing, manufacturing, assembling, labeling, marketing, distribution, sale, implantation, and

removal/replacement of the subject devices implanted into Plaintiffs, to ensure the safety of the products and to ensure that the consuming public, including Plaintiffs and Plaintiffs' physicians, obtained accurate information and instructions for the safe use of the products.

229. The GUIDANT DEFENDANTS also had an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the subject devices, and otherwise distributing the subject devices. Defendants' acts, as aforestated, constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom and from parallel state law requirements, under theories of negligence per se. Plaintiffs, as purchasers and users of the subject devices, are within the class of persons the statutes and regulations described above are designed to protect and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

230. At all material times, the defendants also had a duty to protect Plaintiffs' privacy during the implantation and removal/replacement of the subject devices by not allowing unauthorized personnel to which Plaintiffs did not consent in the operative suite, which defendants breached when they allowed GUIDANT sales representatives in the surgical suite during Plaintiffs' initial implantation procedures and/or removal procedures.

231. At all material times, defendants knew, or in the exercise of reasonable care should have known, that the subject devices could and would cause injury and/or death to patients, such as Plaintiffs, if they were not properly tested, designed, manufactured, assembled, labeled, distributed, marketed, sold, implanted, removed/replaced and warned about, which again the defendants breached as aforesaid. Defendants were also negligent in designing, testing, manufacturing, assembling, marketing, distributing, selling, implanting, and removing/replacing the subject devices.

232. The defendants, and each of them, were also negligent in their supervision, utilization and installation of the defibrillators being implanted in Plaintiffs. In failing to properly supervise, utilize and install the subject devices the defendants, and each of them, failed

in any way to take steps to prevent Plaintiffs' injuries, as described herein, from occurring.

233. The defendants, and each of them, were negligent in their supervision, utilization, removal and replacement of the defibrillators being removed from Plaintiffs. In failing to properly supervise, utilize, remove and replace the subject devices the defendants, and each of them, failed in any way to take steps to prevent Plaintiffs' injuries, as described herein, from occurring.

234. Defendants were also negligent and otherwise careless in letting a non-medical representative of GUIDANT DEFENDANTS invade Plaintiffs' privacy by allowing, without Plaintiffs' consent, the representative to be present in the operating room during the implant, removal/replacement of the subject devices, obtaining personal information regarding Plaintiffs in violation of privacy laws and/or also improperly taking the subject devices from Plaintiffs, so that Plaintiffs could not test and/or examine the subject devices.

235. Each of the following acts and omissions herein alleged were negligently performed or omitted by defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to, negligent research, negligent testing, negligent design, negligent manufacture, negligent implantation, negligent removal and replacement, negligent failure to give adequate instructions for the safe use, negligent failure to give adequate warnings to Plaintiffs, Plaintiffs' physicians, and the public in general of the potentially dangerous, defective, and unsafe propensities of the subject devices and of the risks associated with their use, and negligence in permitting a non-medical representative of GUIDANT DEFENDANTS invade Plaintiffs' privacy.

236. As a direct and proximate result of the aforesaid tortious conduct of the defendants, and as a direct and legal result of the negligence, carelessness, and other wrongdoing, actions, and omissions of the defendants, as described herein, Plaintiffs suffered injuries and damages as alleged herein.

///

///

///

FIFTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTY Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC and DOES 1 through 100, inclusive)

237. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

238. GUIDANT DEFENDANTS impliedly warranted to prospective purchasers and users, including Plaintiffs, by and through statements made by GUIDANT DEFENDANTS or their authorized agents or sales representatives, orally and in publications, advertisements, other direct-to-consumer marketing instruments, package inserts and other written materials intended for physicians, physicians' assistants, medical patients and the general public, that the subject devices were safe, merchantable and fit for the ordinary purposes for which such goods are used.

239. In utilizing the aforementioned product, Plaintiffs relied on the skill, judgment, representations and foregoing implied warranties of GUIDANT DEFENDANTS, and each of them. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended, nor were the products of merchantable quality.

240. GUIDANT DEFENDANTS were fully aware or had reason to know the particular purpose for which Plaintiffs required the goods.

241. Plaintiffs were and are unskilled in the research, design and manufacture of the subject devices and reasonably relied entirely on the skill, judgment and implied warranties of GUIDANT DEFENDANTS in using the subject devices.

242. GUIDANT DEFENDANTS' breach of said implied warranties has directly resulted in the injuries and damages to Plaintiffs as alleged herein.

SIXTH CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC and DOES 1 through 100, inclusive)

243. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

244. GUIDANT DEFENDANTS, and each of them, expressly warranted to prospective purchasers and users, including Plaintiffs, and their agents and physicians, by and through statements made by GUIDANT DEFENDANTS or their authorized agents or sales representatives, orally and in publications, advertisements, other direct-to-consumer marketing instruments, package inserts and other written materials intended for physicians, physicians' assistants, medical patients and the general public, that the Ventak Prizm 2 DR (Model 1861) implantable defibrillator was safe, effective, fit and proper for its intended use.

245. In utilizing the aforementioned products, Plaintiffs relied on the skill, judgment, representations and foregoing express warranties of GUIDANT DEFENDANTS, and each of them. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

246. GUIDANT DEFENDANTS were fully aware or had reason to know the particular purpose for which Plaintiffs required the goods.

247. Plaintiffs were and are unskilled in the research, design and manufacture of the subject devices and reasonably relied entirely on the skill, judgment and express warranties of GUIDANT DEFENDANTS in using the aforementioned subject devices.

248. GUIDANT DEFENDANTS' breach of said express warranty has directly resulted in the injuries and damages to Plaintiffs as alleged herein.

SEVENTH CAUSE OF ACTION
(FRAUD, DECEIT AND FRAUDULENT CONCEALMENT Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC and DOES 1 through 100, inclusive)

249. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

250. At all material times, GUIDANT DEFENDANTS were engaged in the business of designing, testing, manufacturing, assembling, distributing, promoting, and selling implantable defibrillators and pacemakers, including the subject devices implanted into Plaintiffs.

251. GUIDANT DEFENDANTS knew and were aware that their implantable

defibrillators and pacemakers, including the subject devices, were subject to defects that could cause serious bodily injury and/or death.

252. GUIDANT DEFENDANTS made misrepresentations and omissions of material fact in the labeling, instructions, product inserts, advertising, and promotional materials concerning the safety and use of their implantable defibrillators and pacemakers, including the subject devices implanted into Plaintiffs, to the public, including Plaintiffs and Plaintiffs' physicians.

253. At all times relevant to this action, GUIDANT DEFENDANTS knew that their representations were in fact false and misleading, and omitted material facts concerning the safety and use of their products. The true and accurate facts known by and intentionally concealed by GUIDANT DEFENDANTS were that the subject devices were susceptible and subject to malfunctions that could and would result in the permanent loss of shock therapy and/or pacing, which if it occurred would lead to death and/or serious injury. This information was known to GUIDANT DEFENDANTS, and each of them, and GUIDANT DEFENDANTS intentionally withheld this information from physicians who prescribed the products and from consumers, including Plaintiffs, who purchased and used the products.

254. At all times during which GUIDANT DEFENDANTS made the above mentioned intentional concealments and misrepresentations to consumers, including Plaintiffs, and their physicians, GUIDANT DEFENDANTS made the misrepresentations with the specific intent to deceive consumers, including Plaintiffs, and their physicians so as to induce them to choose GUIDANT DEFENDANTS' products over other implantable defibrillators and pacemakers.

255. Plaintiffs had no knowledge of the falsity of GUIDANT DEFENDANTS' misrepresentations or the existence of its intentional concealments and in reliance upon GUIDANT DEFENDANTS' misrepresentations believed the subject devices to be effective and safe for consumption and use for the treatment of Plaintiffs' medical conditions.

256. Plaintiffs reasonably relied upon GUIDANT DEFENDANTS' misrepresentations and were induced to and did in fact consume and use the subject devices to treat Plaintiffs' medical conditions. Plaintiffs would not have consumed and used such products if Plaintiffs had

known and had been informed of the true facts concerning the aforementioned defects and the potential for serious injury and/or death.

257. Plaintiffs justifiably and reasonably relied upon GUIDANT DEFENDANTS' misrepresentations because the GUIDANT DEFENDANTS were in a special and fiduciary relationship to Plaintiffs in that GUIDANT DEFENDANTS held themselves out to have experience in the field of medical devices and knew that patients like Plaintiffs needed and were seeking effective medical devices for the treatment of certain medical conditions, including the conditions for which Plaintiffs used the device. Plaintiffs' reliance upon GUIDANT DEFENDANTS' misrepresentations was reasonable, as Plaintiffs, at all times relevant to this action, did not have the knowledge and/or expertise necessary to independently evaluate whether or not the subject devices that Plaintiffs were prescribed and used were, in fact, safe for human consumption and use.

258. As a direct and proximate result of the foregoing fraudulent and deceitful conduct by GUIDANT DEFENDANTS, and each of them, Plaintiffs purchased, consumed and used the subject devices identified herein, and Plaintiffs sustained the injuries and damages set forth above.

259. The aforementioned acts of the GUIDANT DEFENDANTS, which were performed, authorized and/or ratified by GUIDANT DEFENDANTS' officers, directors and/or managing agents, were willful, wanton, malicious, fraudulent, and oppressive, as defined by California Civil Code Section 3294, and evidence a flagrant disregard for human life, therefore justifying an award of exemplary and punitive damages.

EIGHTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC and DOES 1 through 100, inclusive)

260. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

261. GUIDANT DEFENDANTS falsely represented to Plaintiffs and Plaintiffs' physicians that the subject devices were safe when used as intended. These representations, that

the devices were safe for their intended uses when used as instructed and as labeled, were false, as the subject devices were, in fact, dangerous to the health of consumers, including Plaintiffs, when used as intended.

262. GUIDANT DEFENDANTS failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of the subject devices and otherwise failed to exercise reasonable care in communicating the information to Plaintiffs and Plaintiffs' physicians.

263. In reasonable reliance upon the GUIDANT DEFENDANTS' misrepresentations, Plaintiffs were induced to, and did, use the subject devices.

264. As a direct and proximate result of GUIDANT DEFENDANTS' misrepresentations, Plaintiffs sustained the injuries and damages set forth above.

265. The aforementioned acts of GUIDANT DEFENDANTS, which were performed, authorized and/or ratified by GUIDANT DEFENDANTS' officers, directors and/or managing agents, were willful, wanton, malicious, fraudulent, and oppressive, as defined by California Civil Code Section 3294, and evidence a flagrant disregard for human life, therefore justifying an award of exemplary and punitive damages.

NINTH CAUSE OF ACTION
(INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC and DOES 1 through 100, inclusive)

266. Plaintiffs incorporate by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

267. The aforementioned conduct of GUIDANT DEFENDANTS is sufficiently outrageous in that it exceeds all reasonable bounds of decency in a civilized society.

268. In committing the aforesaid outrageous acts, GUIDANT DEFENDANTS acted with the intent to cause or with the reckless disregard of the probability of causing severe and serious emotional distress to Plaintiffs.

269. As a direct and proximate result of the aforesaid tortious conduct of GUIDANT DEFENDANTS, and as a direct and legal result of the negligence, carelessness, and other

wrongdoing, actions, and omissions of the GUIDANT DEFENDANTS, as described herein, Plaintiffs sustained the injuries and damages set forth above.

270. The aforementioned acts of GUIDANT DEFENDANTS, which were performed, authorized and/or ratified by GUIDANT DEFENDANTS' officers, directors and/or managing agents, were willful, wanton, malicious, fraudulent, and oppressive, as defined by California Civil Code Section 3294, and evidence a flagrant disregard for human life, therefore justifying an award of exemplary and punitive damages.

WHEREFORE, Plaintiffs demand a jury trial as to all issues so triable and demand judgment against the defendants as follows:

1. General damages against all defendants;

2. All medical, hospital and incidental expenses, according to proof against all defendants;

3. Loss of earnings and earnings capacity, past and future, against all defendants;

4. For costs of suit incurred herein against all defendants;

5. For punitive damages as the jury may deem just and proper only to defendants GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC. and DOES 1 through 100;

6. Pre-judgment and post-judgment interest on the respective awards against all defendants;

7. For such other and further relief as the Court may deem just and equitable against all defendants.

Dated: June 14, 2006

GILLIN, JACOBSON, ELLIS & LARSEN

By: _____
KRISTIN LUCEY
Attorneys for Plaintiffs
CLIFFORD HOSLER and DALE PATTON