EXHIBIT B2

that Guidant had violated numerous federal regulations in manufacturing the Insignia & Nexus devices and in failing to investigate properly and disclose those defects.

134. 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 (Sept. 22, 2005). According to Guidant, the foreign material was eliminated in Insignia & Nexus devices shipped after March 12, 2004.

135. 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. 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.

136. 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.

137. 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.

138. 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

139. 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.

140. 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.

141. 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.

142. 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.

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

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

143. 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").

144. 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 (Feb. 8, 2006) ("Feb. 8 FDA 483").

145. 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.

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

147. 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.*

148. 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.

149. 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.

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

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

152. 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

153. 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.

154. 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.

155. 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.

156. 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.

157. It was not until July 2005 that the public was officially notified that 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.

158. 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.

159. 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.

160. 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.

161. 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.

162. 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.

163. 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.

164. 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.

165. 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.

166. 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 (June 24, 2005).

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C. Guidant's Deceptive Promotional and Marketing Activities

167. 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.

168. 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

169. Tens of thousands of individuals' lives, including the plaintiff 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.

170. 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.

171. 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.

172. 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:

173. 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.

174. 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.*

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

176. 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 (June 23, 2005).

177. 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).

178. 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. 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

179. 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.

180. 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.

181. 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.

182. 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.

183. 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.

184. 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.

185. 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.

186. 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.

187. 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.

188. 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

189. 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.

190. 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.

191. 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.

192. The Guidant Defendants acted jointly in the concerted tortuous conduct alleged herein.

193. 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.

194. Boston Scientific, by acquiring the Guidant Defendants, apparently with full knowledge of their actions, has assumed the liabilities of the Guidant Defendants.

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FIRST CAUSE OF ACTION

(STRICT LIABILITY – FAILURE TO WARN Against Defendants GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC CORPORATION, ST. JOSEPH HOSPITAL OF ORANGE and DOES 1 through 100, inclusive)

195. Plaintiff incorporates by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

196. At all times herein mentioned, defendants developed, designed, researched, manufactured, assembled, distributed, promoted, supplied, sold and/or otherwise introduced into the "chain of commerce" the device implanted in Plaintiff, hereinafter the subject device.

197. At all material times, the subject device implanted into the plaintiff on or about December 3, 2001 was designed, manufactured, assembled, distributed, promoted, sold and supplied by defendants, was defective due to inadequate warning or instruction in that defendants failed to conform with federal requirements and defendants knew or should have known that the product created significant risks of serious bodily harm and/or death to consumers and defendants failed to use reasonable care to warn, give adequate warning or provide facts describing the dangerous propensities of the product to consumers, their physicians, and those whom defendants could expect to use the product or be endangered by its probable use. defendants, knowing that their product could cause serious injury and/or death, continued to aggressively market, promote, distribute, and sell the dangerously defective product.

198. Absent proper and adequate warning and instruction by defendants, ordinary consumers, such as Plaintiff, would not have recognized the risks of the subject device, as described herein, and Plaintiff did not recognize such risks.

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

200. Because information concerning the inherently dangerous characteristics of the subject device was unknown to and concealed from the general public, including Plaintiff and Plaintiff's physicians, 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 Plaintiff.

201. The subject device surgically implanted in Plaintiff was used in a way that was reasonably foreseeable to defendants, and was in substantially the same condition as when it left possession of defendants.

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

203. As a direct and proximate result of the acts, omissions, negligence, carelessness, and wrongful and tortious conduct of the defendants, as described herein, Plaintiff has and may sustain serious, severe and permanent personal injuries and damages; serious and severe emotional distress, which is and has become manifested in the form of nightmares and/or crying and/or withdrawal and/or depression and/or the like; severe distress about present and future injuries from the defective device, the explant surgery, the fact that Plaintiff can only have so many replacement surgeries, and the risk of further thrombosis, heart attacks, strokes, and/or further complications.

204. As a direct and proximate result of the acts, omissions, negligence, carelessness, and wrongful and tortious conduct of the defendants, as described herein, Plaintiff was compelled to and did employ the services of hospitals, physicians, surgeons, nurses, and the like to care for and treat Plaintiff and did incur hospital, medical, professional and incidental expenses, and Plaintiff is informed and believes and therein alleges that Plaintiff will unnecessarily, by reason of Plaintiff's injuries, incur additional like expenses for an indefinite period of time in the future.

205. As a direct and proximate result of the acts, omissions, negligence, carelessness, and wrongful and tortious conduct of the defendants, as described herein, Plaintiff has been prevented from attending to Plaintiff's usual occupation, thereby sustaining a loss of income, the duration and extent of which is yet undetermined, and Plaintiff is informed and believes and upon such information and belief alleges that Plaintiff will be prevented from attending to said usual occupation for an indefinite period of time in the future and will incur an additional loss of income; and Plaintiff has sustained a loss of earning capacity.

206. Plaintiff, is informed and believes, and based on upon such information and belief, alleges that Plaintiff's injuries will likely result in some permanent disability, all to Plaintiff's detriment in a sum according to proof.

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

208. The damage amounts sought to be recovered by Plaintiff are well in excess of the jurisdictional minimum for this Court.

209. The aforementioned acts of defendants, which were performed, authorized and/or ratified by 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 CORPORATION, ST. JOSEPH HOSPITAL OF ORANGE and DOES 1 through 100, inclusive)

210. Plaintiff incorporates by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

211. The subject device implanted into the plaintiff on or about December 3, 2001 as designed by defendants was defective.

212. Defendants knew or should have known that the design of the subject device was more dangerous than an ordinary consumer would expect when the product was used in an intended or reasonably foreseeable manner.

213. The subject device implanted in Plaintiff was in substantially the same condition as when it left possession of defendants.

214. Any changes made to the product by Plaintiff's physicians, if any, after the product left the defendants' possession were reasonably foreseeable to defendants.

215. The subject device as designed by Guidant Defendants was defective in that when the product left the hands of defendants, it did not conform to federal requirements, the foreseeable risks of the product exceeded the benefits associated with its design, and it was more dangerous than an ordinary consumer, such as Plaintiff, would expect.

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

217. The aforementioned acts of defendants, which were performed, authorized and/or ratified by 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.

THIRD CAUSE OF ACTION

(STRICT LIABILITY – MANUFACTURING DEFECT Against Defendants, GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC CORPORATION, ST. JOSEPH HOSPITAL OF ORANGE and DOES 1 through 100, inclusive)

218. Plaintiff incorporates by reference each and every allegation within the

preceding paragraphs as though fully set forth herein.

219. The subject device placed into the stream of commerce by defendants, was defective in its manufacture and construction when it left defendants' possession in that it deviated from product specifications, failed to comply with federal requirements, and posed a serious and unreasonable risk of injury and death to foreseeable consumers, such as Plaintiff, when used in an intended or reasonably foreseeable manner.

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

221. The aforementioned acts of defendants, which were performed, authorized and/or ratified by 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.

FOURTH CAUSE OF ACTION

(NEGLIGENCE Against Defendants GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC CORPORATION, ST. JOSEPH HOSPITAL OF ORANGE, and DOES 1 through 100, inclusive)

222. Plaintiff incorporates by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

223. 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 device implanted into the plaintiff and to ensure the safety of the product and to ensure that the consuming public, including Plaintiff and Plaintiff's physicians, obtained accurate information and instructions for the safe use of the

product.

224. The 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 Devices, and otherwise distributing the 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. Plaintiff, as a purchaser and user of the Defendants' 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.

225. At all material times, the defendants also had a duty to protect Plaintiff's privacy during the implantation and removal/replacement of the subject device by not allowing unauthorized personnel which plaintiff did not consent to in the operative suite, which defendants breached when they allowed Guidant sales representatives in the surgical suite during plaintiff's initial implantation procedure and/or removal procedure.

226. At all material times, defendants knew, or in the exercise of reasonable care should have known, that the subject device could and would cause injury and/or death to patients, such as Plaintiff, if it was 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 the designing, testing, manufacturing, assembling, marketing, distributing, selling, implanting, and removing/replacing the device.

227. The defendants, and each of them, were also negligent in their supervision, utilization and installation of the defibrillator being implanted in Plaintiff. In failing to properly supervise, utilize and install the defibrillation the defendants, and each of them, failed in any way to take steps to prevent Plaintiff's injuries, as described herein, from occurring.

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

229. Defendants were also negligent and otherwise careless in letting a non-medical representative of Guidant Defendants invade Plaintiff's privacy by allowing, without Plaintiff's consent, the representative to be present in the operating room during the implant, removal/replacement of the subject device, obtaining personal information regarding Plaintiff in violation of privacy laws and/or also improperly taking the subject device from the plaintiff, so that the plaintiff could test and/or examine the subject device.

230. 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 the plaintiff, Plaintiff's physicians, and the public in general of the potentially dangerous, defective, and unsafe propensities of the subject device and of the risks associated with its use, and negligence in permitting a non-medical representative of Guidant Defendants invade Plaintiff's privacy.

231. 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, Plaintiff suffered injuries and damages as alleged herein.

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FIFTH CAUSE OF ACTION

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

232. Plaintiff incorporates by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

233. Guidant Defendants impliedly warranted to prospective purchasers and users, including Plaintiff, 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 device was safe, merchantable and fit for the ordinary purposes for which such goods are used.

234. In utilizing the aforementioned product, Plaintiff 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 product was not safe and was unfit for the uses for which it was intended, nor was the product of merchantable quality.

235. Guidant Defendants were fully aware or had reason to know the particular purpose for which Plaintiff required the goods.

236. Plaintiff was and is unskilled in the research, design and manufacture of the aforementioned product and reasonably relied entirely on the skill, judgment and implied warranties of Guidant Defendants in using the aforementioned product.

237. Guidant Defendants' breach of said implied warranties has directly resulted in the injuries and damages to Plaintiff as alleged herein.

SIXTH CAUSE OF ACTION

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

238. Plaintiff incorporates by reference each and every allegation within the preceding

paragraphs as though fully set forth herein.

239. Guidant Defendants, and each of them, expressly warranted to prospective purchasers and users, including Plaintiff, 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.

240. In utilizing the aforementioned product, Plaintiff 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 product was not safe and was unfit for the uses for which it was intended.

241. Guidant Defendants were fully aware or had reason to know the particular purpose for which Plaintiff required the goods.

242. Plaintiff was and is unskilled in the research, design and manufacture of the aforementioned product and reasonably relied entirely on the skill, judgment and express warranties of Guidant Defendants in using the aforementioned product.

243. Guidant Defendants' breach of said express warranty has directly resulted in the injuries and damages to Plaintiff as alleged herein.

SEVENTH CAUSE OF ACTION

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

244. Plaintiff incorporates by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

245. 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 device implanted into the plaintiff.

246. Guidant Defendants knew and were aware that their implantable defibrillators and pacemakers, including the subject device, were subject to defects that could cause serious bodily injury and/or death.

247. 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 device implanted into the plaintiff to the public, including Plaintiff and Plaintiff's physicians.

248. 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 product. The true and accurate facts known by and intentionally concealed by Guidant Defendants were that the subject device was susceptible and subject to a malfunction 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 product and from consumers, including Plaintiff, who purchased and used the product.

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

250. Plaintiff 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 device to be effective, and safe for consumption and use for the treatment of Plaintiff's medical condition.

251. Plaintiff reasonably relied upon Guidant Defendants' misrepresentations and was induced to and did in fact consume and use the subject device to treat Plaintiff's medical

condition. Plaintiff would not have consumed and used such product if Plaintiff had known and had been informed of the true facts concerning the aforementioned defects and the potential for serious injury and/or death.

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

253. As a direct and proximate result of the foregoing fraudulent and deceitful conduct by Guidant Defendants, and each of them, Plaintiff purchased, consumed and used the product identified herein, and Plaintiff sustained the injuries and damages set forth above.

254. 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* § 3294, and evidences 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 CORPORATION and DOES 1 through 100, inclusive)

255. Plaintiff incorporates by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

256. Guidant Defendants falsely represented to Plaintiff and Plaintiff's physicians that the subject device was safe when used as intended. These representations, that the device was

safe for its intended use when used as instructed and as labeled were false, as the device was, in fact, dangerous to the health of consumers, including Plaintiff, when used as intended.

257. Guidant Defendants failed to exercise reasonable care in ascertaining the accuracy of the information regarding the safe use of the subject device and otherwise failed to exercise reasonable care in communicating the information to Plaintiff and Plaintiff's physicians.

258. In reasonable reliance upon the Guidant Defendants' misrepresentations, Plaintiff was induced to, and did, use the subject device.

259. As a direct and proximate result of Guidant Defendants' misrepresentations, Plaintiff sustained the injuries and damages set forth above.

260. 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.

NINTH CAUSE OF ACTION

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

261. Plaintiff incorporates by reference each and every allegation within the preceding paragraphs as though fully set forth herein.

262. The aforementioned conduct of Guidant Defendants is sufficiently outrageous in that it exceeds all reasonable bounds of decency in a civilized society.

263. 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 Plaintiff.

264. 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, Plaintiff 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* § 3294, and evidences a flagrant disregard for human life, therefore justifying an award of exemplary and punitive damages.

WHEREFORE, Plaintiff demands a jury trial as to all issues so triable and demands 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., BOSTON SCIENTIFIC CORPORATION 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 28, 2006

GIANNI ✦ PETOYAN

By: _____
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