

EXHIBIT B2

1 Urgent Medical Device Safety Information & Corrective Action: Ventak Prizm® 2 DR,
2 Model 1861 (June 17, 2005) ("June 17 Dear Doctor Letter").

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

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

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

20 82. Finally, after public disclosures of Guidant's misconduct, on June or July of
21 2005, Guidant applied for FDA approval to replace polyimide with PEEK in certain devices,
22 such as the Ventak Prizm 2 DR 1861. The FDA approved this change in August 2005 and, in
23 October 2005, described it as "replacing the insulating material on the feedthru wires with a
24 different material that has better degradation properties." FDA, Update of FDA Preliminary
25 Public Health Notification*: Guidant Ventak Prizm 2 DR and Contak Renewal Implantable
26 Cardioverter Defibrillators (Oct. 13, 2005).

27 83. In Guidant's May 23, 2005, communication with doctors, it did not
28 recommend replacement of the Ventak Prizm devices. *See* May 25, 2005 Guidant Press

1 Release. Moreover, reports suggest that Guidant's sales representatives continued to assure
2 physicians that it was unnecessary to replace the defective devices in their individuals.

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

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

20 86. As of December 2005, the FDA reported that two deaths had been linked to
21 the Ventak Prizm 2 DR 1861. While Guidant reported a predicted occurrence rate of 0.10%
22 to 0.24% in Ventak Prizm DR 1861 devices that were manufactured on or before April 16,
23 2002, it stated that its computations of potential occurrence rate could be artificially low and
24 that its predictive modeling is "inherently uncertain." Guidant also disclosed that a failure
25 had been associated with a Ventak Prizm 2 DR 1861 that was manufactured after April 16,
26 2002.

27 87. At all times relevant to this action, Guidant knew, and had reason to know,
28 that the Ventak Prizm 2 DR 1861 was not safe for the individuals for whom they were

1 prescribed and implanted, because the devices malfunctioned, and therefore failed to operate
2 in a safe and continuous manner, causing serious medical problems and, in certain
3 individuals, catastrophic injuries and deaths.

4 **C. Contak Renewal 1 and 2**

5 88. Guidant manufactured CRT-Ds known as Contak Renewal Model H135 and
6 Contak Renewal 2 Model H155 (hereinafter collectively "Contak Renewal 1 & 2").

7 89. In or before November 2003, Guidant became aware that the Contak Renewal
8 1 & 2 were prone to short-circuiting problems similar to those found in the Ventak Prizm 2
9 DR 1861. Like the Ventak Prizm 2 DR 1861, the Contak Renewal 1 & 2 included polyimide
10 tubing.

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

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

21 92. In January 2005, Guidant considered withdrawing Contak Renewal 1 & 2
22 devices from the market because of the defects, but concluded that Guidant would not
23 disclose the Contak Renewal 1 & 2 defect or withdraw the devices from the market because
24 of the number of defective devices that would be implanted by the time of any such action.

25 93. On June 17, 2005, only after Guidant had been forced to disclose the Ventak
26 Prizm 2 DR 1861 defect and the FDA had initiated a review of Guidant's other Devices, did
27 Guidant issue a letter to doctors disclosing the defective nature of the Contak Renewal 1 & 2.
28 Specifically, as to these devices, Guidant stated that its laboratory analysis had proven that

1 the Contak Renewal 1 & 2 had failed due to "deterioration in a wire insulator within the lead
2 connector block [which,] in conjunction with other factors, could cause a short circuit and
3 loss of device function due to diversion of therapy energy away from the heart and into
4 device circuitry." Guidant Corp., Urgent Medical Device Safety Information & Corrective
5 Action: Contak Renewal Model H135 and Contak Renewal 2 Model H155 Devices
6 Manufactured on or Before August 26, 2004 (June 17, 2005) ("June 17 Contak Renewal 1 &
7 2 Letter").

8 94. Guidant stated that there is no way of predicting whether "any particular
9 device will fail." *Id.* According to the June 17 Contak Renewal 1 & 2 Letter, fifteen reports
10 of the malfunction had been confirmed, at least, one of which was fatal, and approximately
11 16,000 of the devices had been implanted worldwide. *See id.*

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

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

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

22 98. Once again, despite the fact that Guidant made manufacturing changes on or
23 around August 26, 2004, which it represented had corrected the defect in the Contak Renewal
24 1 & 2 devices, Guidant failed to inform physicians, patients, and the public until the June 17
25 Contak Renewal 1 & 2 Letter.

26 99. In June 2005, Guidant recommended that physicians assess whether to replace
27 the Contak Renewal 1 & 2 devices. In September 2005, Guidant recommended that
28 physicians reassess device replacement "as a result of the increased projected rate of

1 occurrence." Guidant Corp., Advisory Update: Contak Renewal and Contak Renewal 2,
2 Models H135 and H155 (Sept. 12, 2005).

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

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

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

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

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

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

24 **D. Contak Renewal 3 and 4**

25 106. Guidant also manufactured Contak Renewal 3, Contak Renewal 3 HE, Contak
26 Renewal 4, Contak Renewal 4 HE, Contak Renewal 3 AVT, Contak Renewal 3 AVT HE,
27 Contak Renewal 4 AVT, Contak Renewal 4 AVT HE, Renewal RF, and Renewal RF HE
28 CRT-Ds (hereafter referred to as "Contak Renewal 3 & 4").

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

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

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

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

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

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

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

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

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

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

25 116. The FDA originally classified Guidant's actions with regard to the AVT
26 devices as a Class II recall. However, after Guidant incorrectly advised the medical
27 community of a programming change that would actually increase the likelihood that latching
28 would occur, the FDA converted Guidant's actions with regard to the AVT devices to a Class

1 I recall. According to the FDA, approximately 21,000 of the devices have been implanted
2 worldwide.

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

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

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

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

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

22 121. Guidant first disclosed the problem with degradation of the hermetic sealing
23 component in a letter to doctors on July 18, 2005. See Guidant Corp., Urgent Medical
24 Device Safety Information & Corrective Action: Pulsar Max, Pulsar, Discovery, Meridian,
25 Pulsar Max II, Discovery II, Virtus Plus II, Intelis II, and Contak TR Devices (July 18, 2005)
26 ("July 18 Dear Doctor Letter"). According to Guidant, the leakage into the pacemaker seal
27 can lead to premature battery depletion ("resulting in loss of telemetry and/or loss of pacing
28 output without warning") and inappropriate accelerometer function (resulting in sustained

1 pacing at the maximum rate and lack of appropriate accelerometer rate response during
2 activity). *Id.*

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

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

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

20 125. Guidant also advised that individuals should seek attention immediately, "if
21 they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have new
22 or increased symptoms of heart failure." in the July 18 Dear Doctor Letter.

23 126. The explanation recommended by Guidant to address the defects in the
24 Guidant Pacemakers will subject thousands of individuals to explantation surgery and related
25 risks and trauma.

26 127. Guidant has also recommended that individuals implanted with the Guidant
27 Pacemakers consider increasing the frequency of medical visits to increase the likelihood of
28 detecting a failure that has already occurred.

1 128. The FDA has classified Guidant's action with respect to the Guidant
2 Pacemakers as a Class I recall.

3 129. Since July 2005, Guidant has issued further advisories about potential
4 hermetic seal degradation in the Guidant Pacemakers. Specifically, on January 23, 2006,
5 Guidant announced that the Guidant Pacemakers may also be subject to hermetic seal
6 degradation because of a manufacturing error, in which hermetic sealing components
7 susceptible to gradual degradation were mistakenly mixed with a much larger group of non-
8 susceptible components. Guidant stated that there is no way to determine which of the
9 54,000 potentially affected devices might be defective due to the use of improper materials.

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

15 **G. Insignia and Nexus Pacemakers**

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

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

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

26 134. In the first failure mode, which Guidant first disclosed on September 22, 2005,
27 up to 49,500 Insignia & Nexus devices may be subject to failure due to "foreign material
28 within a crystal timing component." Guidant Corp., Important Medical Device Safety

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

3 135. In the second failure mode, which Guidant first disclosed on September 22,
4 2005, up to 341,000 Insignia & Nexus devices may exhibit a failure of pacing for which
5 Guidant could not determine the cause. While Guidant asserted that this defect had only been
6 noted at implant, at least one individual had experienced cardiac arrest during attempted
7 implant of a defective Insignia & Nexus device.

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

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

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

20 **H. Additional Recent Recalls/Advisories**

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

1 regarding the Contak Renewal 3 RF and Contak Renewal 4 RF as a recall.

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

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

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

23 **V. GUIDANT'S PAST AND PRESENT ILLEGAL AND REPREHENSIBLE**
24 **CONDUCT**

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

26 143. The FDA conducted an inspection of Guidant's facilities during the time
27 period of August 22, 2005 to September 1, 2005. At the conclusion of the inspection, the
28 FDA issued a 483 Inspection Report ("FDA 483"), in which it detailed violations of federal

1 regulations by Guidant. See FDA 483 Inspection Report (Sept. 1, 2005) ("Sept. 1 FDA
2 483").

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

6 145. Included in the Sept. 1 FDA 483 for Guidant were the following fifteen
7 observations of violations noted by FDA:

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

1 existing and potential causes of nonconforming product and other quality
2 problems;"

3 • processes have not been approved and electronic records do not meet
4 employee accountability/responsibility policy and signature manifestation
5 requirements to ensure that they are trustworthy, reliable and generally
6 equivalent to paper records;

7 • "[t]he document control procedures do not designate an individual to review
8 documents for adequacy and approve them prior to issuance;"

9 • "[r]ework and reevaluation activities have not been documented in the device
10 history records;"

11 • "[d]ocument control procedures are not complete;" and

12 • the device history record does not include complete acceptance records that
13 demonstrate the device is manufactured in accordance with the device master
14 record.

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

17 147. From December 2005 to February 2006, the FDA again inspected Guidant's
18 manufacturing facilities and found further egregious violations of basic manufacturing
19 standards fundamental to federal and state law. *See* Feb. 8 FDA 483. Specifically, the FDA
20 found that Guidant had failed to disclose the AVT device defects that it had known about
21 since May 2002 and had attempted to correct through revised software implemented by May
22 2004. *See id.*

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

27 149. Moreover, with respect to each of the Guidant Devices at issue in this
28 litigation, Defendants failed to comply with FDA regulations and the Conditions of Approval

1 relating to relevant PMA and PMA Supplements.

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

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

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

10 **B. Guidant's Concealment of the Device Defects**

11 153. Guidant's failure to disclose accurately and adequately the known defects in
12 the Devices and concealment of known defects from the FDA, the medical community, and
13 from Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of
14 limitation.

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

19 155. It was not until June 17, 2005, that the public was officially notified by the
20 FDA that the agency was recalling Contak Renewal 1 & 2 devices. At no point prior to June
21 17, 2005, did Guidant notify any Plaintiff, the medical community, or the public that the
22 Contak Renewal 1 & 2 were defective.

23 156. It was not until June 17, 2005, that the public was notified by the FDA that
24 AVTs were defective and were resulting in memory failures. At no point prior to June 17,
25 2005, did Guidant notify any Plaintiff, the medical community, or the public that the AVTs
26 were defective.

27 157. It was not until July 2005 that the public was officially notified that the
28 Guidant Pacemakers were defective. At no point prior to July 22, 2005 did Guidant notify

1 any Plaintiff, the medical community, the FDA, or the public that the Guidant Pacemakers
2 were defective.

3 158. Meanwhile, although Guidant regularly issued Product Performance Reports
4 purporting to disclose information regarding the Devices, it was not until late 2005 that such
5 Product Performance Reports included any information from which a reader could discern
6 that Guidant was aware of potentially life-threatening malfunctions that could occur in the
7 Devices.

8 159. Guidant's failure to properly disclose the known defects in the Devices and
9 their active concealment of the known defects from the FDA, the medical community, and
10 Plaintiffs constitutes fraudulent concealment that equitably tolls applicable statutes of
11 limitation.

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

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

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

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

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

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

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

22 **C. Guidant's Deceptive Promotional and Marketing Activities**

23 167. Consistent with their failure to disclose defects and its other concealments of
24 the defects in the Devices, throughout the years that it was manufacturing and selling the
25 Devices, Defendants' promotional, marketing, and advertising materials consistently
26 concealed the defects about which it knew or should have known, as set forth at length above.
27 Routinely, the information provided in those materials was materially misleading and
28 incomplete. While otherwise affirming aspects of the Devices, the defects and complications

1 associated with the devices were consistently never disclosed. By way of another example, in
2 marketing brochures, Guidant affirmatively and specifically touted the longevity of its ICDs
3 and pacemakers again without disclosing its defects and complications.

4 168. In reality, Defendants' devices did not have such longevity and by virtue of the
5 defects inherent in the products, Plaintiffs and many other individuals have had to have their
6 devices prematurely explanted long before the expected life of the products had run.

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

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

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

15 171. Guidant sales representatives consistently visit with individuals and
16 physicians, attempting to persuade them that, notwithstanding the various FDA Class I
17 recalls, explantation of the Devices is unnecessary.

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

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

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

1 175. According to the June 17, 2005 Dear Doctor Letter, an additional
2 20,950 devices were subject to failure. See June 17 Dear Doctor Letter.

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

7 177. FDA estimates have put the total number of potentially affected Devices at
8 87,600, including 20,600 Devices with deteriorated electrical insulation (such as the Ventak
9 Prizm 2 DR 1861); 21,000 Devices with the "latching" error (such as the AVTs); and 46,000
10 Devices with the malfunctioning magnetic switch (such as the Contak Renewal 3 & 4).

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

18 **E. Guidant's History of Criminal Misconduct**

19 179. In June 2003, Guidant's then wholly-owned subsidiary, Endovascular
20 Technologies, Inc. ("EVT"), agreed to plead guilty to nine felony counts of introducing
21 misbranded medical devices into interstate commerce, in violation of 21 U.S.C. § 331(a), and
22 one felony count of making false statements to the FDA, as well as the payment of \$92.4
23 million to settle the charges. The plea agreement related to a medical device known as the
24 Ancure Endograft System, which was released in September 1999, withdrawn in March
25 2001, released again in August 2001, and finally withdrawn in March 2003. The device was
26 used to treat abdominal aortic aneurysms, a potentially life-threatening condition. Guidant's
27 EVT subsidiary became aware of serious and sometimes fatal malfunctions in the device's
28 delivery system, yet concealed information about the malfunctions from the FDA, physicians,

1 and the public. At least seventy-six deaths and dozens of invasive surgeries resulted from the
2 malfunctions.

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

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

21 182. Despite the obligations described above in the Corporate Integrity Agreement
22 executed by Guidant on June 30, 2003, Guidant failed to satisfy those obligations in its
23 manufacture and sale of the Devices.

24 183. For example, as to the Devices, Guidant failed to timely report adverse events;
25 failed to timely conduct failure investigations and analysis; failed to timely report any and all
26 information concerning product failures and corrections; failed to timely and fully inform
27 FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device
28 failures necessitating a labeling, manufacturing or device modification; failed to conduct

1 necessary design validation; and sold a misbranded and adulterated product.

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

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

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

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

27 187. In the summer of 2005, GUIDANT CORPORATION established an
28 Independent Panel of experts to recommend guidelines for surveillance and assessment of

1 malfunctions of its implantable defibrillators and pacemakers, and how and when to
2 communicate safety-related information to physicians and patients. On or about March 20,
3 2006, the Independent Panel issued its Report, which outlined, among other things, a
4 "...series of problems requiring attention." The Report, in part, noted the following
5 problems:

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

11 b. "The Product Performance Engineer positions (at CRM) have been
12 chronically understaffed." Report, p. 54. (Product Performance Engineers are responsible for
13 evaluating and classifying device complaints, as well as integrating hardware findings
14 generated by a reliability engineer, and consult with others as needed to determine the
15 relevance of the problem.) Report, p. 12.

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

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

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

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

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

28 h. "There are no (medical) advisory boards that serve primarily as

1 advocates for quality and patient safety." Report, p. 74.

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

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

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

11 188. As outlined above, the Independent Panel hired by Guidant found multiple
12 problems with Guidant's quality control processes – particularly with respect to post-market
13 evaluation of the Devices – which are not consistent with appropriate concern for patients
14 and quality.

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

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

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

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

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

10 193. At all times herein mentioned, the officers and/or directors of the Guidant
11 Defendants named herein participated in, authorized and/or directed the production and
12 promotion of the aforementioned Devices when they knew, or with the exercise of reasonable
13 care and diligence should have known, of the hazards and dangerous propensities of said
14 Devices, and thereby actively participated in the tortuous conduct that resulted in the injuries
15 suffered by Plaintiffs.

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

18 **FIRST CAUSE OF ACTION**

19 **(STRICT LIABILITY – FAILURE TO WARN Against Defendants GUIDANT**
20 **CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS,**
21 **INC., BOSTON SCIENTIFIC CORPORATION, ORANGE COAST MEMORIAL**
22 **MEDICAL CENTER and DOES 1 through 100, inclusive)**

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

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

28 197. At all material times, the subject device implanted into the plaintiff on or

1 about February 10, 2003 was designed, manufactured, assembled, distributed, promoted, sold
2 and supplied by defendants, was defective due to inadequate warning or instruction in that
3 defendants failed to conform with federal requirements and defendants knew or should have
4 known that the product created significant risks of serious bodily harm and/or death to
5 consumers and defendants failed to use reasonable care to warn, give adequate warning or
6 provide facts describing the dangerous propensities of the product to consumers, their
7 physicians, and those whom defendants could expect to use the product or be endangered by
8 its probable use. defendants, knowing that their product could cause serious injury and/or
9 death, continued to aggressively market, promote, distribute, and sell the dangerously
10 defective product.

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

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

18 200. Because information concerning the inherently dangerous characteristics of
19 the subject device was unknown to and concealed from the general public, including Plaintiff
20 and Plaintiff's physicians, defendants were under a duty, yet intentionally failed to disclose to
21 patients, the consuming public, and the medical community that their products were
22 defective, unsafe, and inherently dangerous for their intended use by consumers such as
23 Plaintiff.

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

27 202. As a direct and proximate result of the aforesaid tortious conduct of
28 defendants, and as a direct and legal result of the negligence, carelessness, and other

1 wrongdoing, actions and omissions of defendants, as described herein, Plaintiff suffered
2 injuries and damages as alleged herein.

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

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

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

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

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

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

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

11 **SECOND CAUSE OF ACTION**

12 **(STRICT LIABILITY – DESIGN DEFECT Against Defendants GUIDANT**
13 **CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS,**
14 **INC., BOSTON SCIENTIFIC CORPORATION, ORANGE COAST MEMORIAL**
15 **MEDICAL CENTER and DOES 1 through 100, inclusive)**

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

18 211. The subject device implanted into the plaintiff on or about February 10, 2003
19 as designed by defendants was defective.

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

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

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

27 215. The subject device as designed by defendants was defective in that when the
28 product left the hands of defendants, it did not conform to federal requirements, the

1 foreseeable risks of the product exceeded the benefits associated with its design, and it was
2 more dangerous than an ordinary consumer, such as Plaintiff, would expect.

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

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

12 **THIRD CAUSE OF ACTION**

13 (STRICT LIABILITY – MANUFACTURING DEFECT Against Defendants
14 GUIDANT CORPORATION, GUIDANT SALES CORPORATION, CARDIAC
15 PACEMAKERS, INC., BOSTON SCIENTIFIC CORPORATION, ORANGE COAST
16 MEMORIAL MEDICAL CENTER and DOES 1 through 100, inclusive)

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

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

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

28 221. The aforementioned acts of defendants, which were performed, authorized

1 and/or ratified by defendants' officers, directors and/or managing agents were willful,
2 wanton, malicious fraudulent, and oppressive, as defined by *California Civil Code* § 3294,
3 and evidences a flagrant disregard for human life, therefore justifying an award of exemplary
4 and punitive damages.

5 **FOURTH CAUSE OF ACTION**

6 **(NEGLIGENCE Against Defendants GUIDANT CORPORATION, GUIDANT SALES**
7 **CORPORATION, CARDIAC PACEMAKERS, INC., BOSTON SCIENTIFIC**
8 **CORPORATION, ORANGE COAST MEMORIAL MEDICAL CENTER, and DOES**
9 **1 through 100, inclusive)**

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

12 223. At all material times, the defendants had a duty to provide adequate warnings
13 regarding the use of and to exercise reasonable care in all aspects of the designing, testing,
14 manufacturing, assembling, labeling, marketing, distribution, sale, implantation, and
15 removal/replacement of the subject device implanted into the plaintiff and to ensure the
16 safety of the product and to ensure that the consuming public, including Plaintiff and
17 Plaintiff's physicians, obtained accurate information and instructions for the safe use of the
18 product.

19 224. The defendants also had an obligation not to violate the law in the
20 manufacture, design, testing, assembly, inspection, labeling, packaging, supplying,
21 marketing, selling, advertising, preparing for use, warning of the risks and dangers of the
22 Devices, and otherwise distributing the Devices. Defendants' acts, as aforesaid, constitute
23 an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a)
24 and 333(a)(2), and constitute a breach of duty subjecting Defendants to civil liability for all
25 damages arising therefrom and from parallel state law requirements, under theories of
26 negligence per se. Plaintiff, as a purchaser and user of the Defendants' Devices, are within
27 the class of persons the statutes and regulations described above are designed to protect and
28 Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

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

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

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

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

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

1 230. Each of the following acts and omissions herein alleged were negligently
2 performed or omitted by defendants, resulting in a breach of the duties set forth above. These
3 acts and omissions include, but are not restricted to, negligent research, negligent testing,
4 negligent design, negligent manufacture, negligent implantation, negligent removal and
5 replacement, negligent failure to give adequate instructions for the safe use, negligent failure
6 to give adequate warnings to the plaintiff, Plaintiff's physicians, and the public in general of
7 the potentially dangerous, defective, and unsafe propensities of the subject device and of the
8 risks associated with its use, and negligence in permitting a non-medical representative of
9 Guidant Defendants invade Plaintiff's privacy.

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

14 **FIFTH CAUSE OF ACTION**

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

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

20 233. Guidant Defendants impliedly warranted to prospective purchasers and users,
21 including Plaintiff, by and through statements made by Guidant Defendants or their authorized
22 agents or sales representatives, orally and in publications, advertisements, other direct-to-
23 consumer marketing instruments, package inserts and other written materials intended for
24 physicians, physicians' assistants, medical patients and the general public, that the subject device
25 was safe, merchantable and fit for the ordinary purposes for which such goods are used.

26 234. In utilizing the aforementioned product, Plaintiff relied on the skill, judgment,
27 representations and foregoing implied warranties of Guidant Defendants, and each of them. Said
28 warranties and representations were false in that the aforementioned product was not safe and

1 was unfit for the uses for which it was intended, nor was the product of merchantable quality.

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

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

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

9 **SIXTH CAUSE OF ACTION**

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

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

15 239. Guidant Defendants, and each of them, expressly warranted to prospective
16 purchasers and users, including Plaintiff, and their agents and physicians, by and through
17 statements made by Guidant Defendants or their authorized agents or sales representatives, orally
18 and in publications, advertisements, other direct-to-consumer marketing instruments, package
19 inserts and other written materials intended for physicians, physicians' assistants, medical
20 patients and the general public, that the Contak Renewal (Model H135) implantable defibrillator
21 was safe, effective, fit and proper for its intended use.

22 240. In utilizing the aforementioned product, Plaintiff relied on the skill, judgment,
23 representations and foregoing express warranties of Guidant Defendants, and each of them. Said
24 warranties and representations were false in that the aforementioned product was not safe and
25 was unfit for the uses for which it was intended.

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

28 242. Plaintiff was and is unskilled in the research, design and manufacture of the

1 aforementioned product and reasonably relied entirely on the skill, judgment and express
2 warranties of Guidant Defendants in using the aforementioned product.

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

5 **SEVENTH CAUSE OF ACTION**

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

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

11 245. At all material times, Guidant Defendants were engaged in the business of
12 designing, testing, manufacturing, assembling, distributing, promoting, and selling implantable
13 defibrillators and pacemakers, including the subject device implanted into the plaintiff.

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

17 247. Guidant Defendants made misrepresentations and omissions of material fact in
18 the labeling, instructions, product inserts, advertising, and promotional materials concerning the
19 safety and use of their implantable defibrillators and pacemakers, including the subject device
20 implanted into the plaintiff to the public, including Plaintiff and Plaintiff's physicians.

21 248. At all times relevant to this action, Guidant Defendants knew that their
22 representations were in fact false and misleading, and omitted material facts concerning the
23 safety and use of their product. The true and accurate facts known by and intentionally concealed
24 by Guidant Defendants were that the subject device was susceptible and subject to a malfunction
25 that could and would result in the permanent loss of shock therapy and/or pacing, which if it
26 occurred would lead to death and/or serious injury. This information was known to Guidant
27 Defendants, and each of them, and Guidant Defendants intentionally withheld this information
28 from physicians who prescribed the product and from consumers, including Plaintiff, who

1 purchased and used the product.

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

7 250. Plaintiff had no knowledge of the falsity of Guidant Defendants'
8 misrepresentations or the existence of its intentional concealments and in reliance upon Guidant
9 Defendants' misrepresentations believed the subject device to be effective, and safe for
10 consumption and use for the treatment of Plaintiff's medical condition.

11 251. Plaintiff reasonably relied upon Guidant Defendants' misrepresentations and was
12 induced to and did in fact consume and use the subject device to treat Plaintiff's medical
13 condition. Plaintiff would not have consumed and used such product if Plaintiff had known and
14 had been informed of the true facts concerning the aforementioned defects and the potential for
15 serious injury and/or death.

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

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

28 254. The aforementioned acts of the Guidant Defendants, which were performed,

1 authorized and/or ratified by Guidant Defendants' officers, directors and/or managing agents,
2 were willful, wanton, malicious, fraudulent, and oppressive, as defined by *California Civil Code*
3 § 3294, and evidences a flagrant disregard for human life, therefore justifying an award of
4 exemplary and punitive damages.

5 **EIGHTH CAUSE OF ACTION**

6 **(NEGLIGENT MISREPRESENTATION Against Defendants GUIDANT**
7 **CORPORATION, GUIDANT SALES CORPORATION, CARDIAC PACEMAKERS,**
8 **INC., BOSTON SCIENTIFIC CORPORATION and DOES 1 through 100, inclusive)**

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

11 256. Guidant Defendants falsely represented to Plaintiff and Plaintiff's physicians that
12 the subject device was safe when used as intended. These representations, that the device was
13 safe for its intended use when used as instructed and as labeled were false, as the device was, in
14 fact, dangerous to the health of consumers, including Plaintiff, when used as intended.

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

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

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

22 260. The aforementioned acts of Guidant Defendants, which were performed,
23 authorized and/or ratified by Guidant Defendants' officers, directors and/or managing agents,
24 were willful, wanton, malicious, fraudulent, and oppressive, as defined by *California Civil Code*
25 § 3294, and evidences a flagrant disregard for human life, therefore justifying an award of
26 exemplary and punitive damages.

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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 the 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, the 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 the 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 defendants, which were performed, authorized and/or ratified by the 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;

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

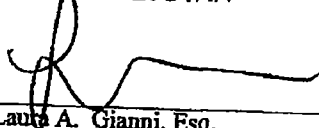
4 6. Pre-judgment and post-judgment interest on the respective awards against all
5 defendants;

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

8
9 Dated: June 28, 2006

GIANNI ♦ PETOYAN

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11 By:

12 
Laura A. Gianni, Esq.
Marcus Petoyan, Esq.

13 Anne Andrews, Esq.
14 John C. Thornton, Esq.
15 ANDREWS & THORNTON

16 Attorneys for Plaintiff
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