EXHIBIT B1

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

GUSTAVO COVARRUBIAS BARRIGA, PLAINTIFF, vs. GUIDANT CORPORATION; GUIDANT SALES CORPORATION; CARDIAC PACEMAKERS, INC.; BOSTON SCIENTIFIC CORPORATION; PROVIDENCE SAINT JOSEPH; and DOES 1 through 100, inclusive, DEFENDANTS.	Case No.: 06355458 **COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL:** 1. STRICT LIABILITY – FAILURE TO WARN; 2. STRICT LIABILITY – DESIGN DEFECT; 3. STRICT LIABILITY – MANUFACTURING DEFECT; 4. NEGLIGENCE; 5. BREACH OF IMPLIED WARRANTY; 6. BREACH OF EXPRESS WARRANTY; 7. FRAUD, DECEIT AND FRAUDULENT CONCEALMENT; 8. NEGLIGENT MISREPRESENTATION; 9. INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS.

Plaintiff, GUSTAVO COVARRUBIAS BARRIGA, by and through his attorneys, Lopez, Hodes, Restaino, Milman & Skikos, for causes of action against defendants, and each of them, alleges the following:

PRELIMINARY ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

I. THE PARTIES AND VENUE ALLEGATIONS

1. Plaintiff, GUSTAVO COVARRUBIAS BARRIGA, is a resident of the State of California, County of Los Angeles. The County of Los Angeles was the County where the products

complained of herein were actually used. At all times herein mentioned, the County of Los Angeles was the site of acts, negligence, and wrongful and tortious conduct that resulted in the injuries and damages complained of as set forth herein.

2. Defendant PROVIDENCE SAINT JOSEPH is, and at all times herein mentioned was, a corporation organized and existing under the laws of the State of California and a resident of the State of California, County of Los Angeles. Plaintiff is informed and believes and thereon alleges, that at all times herein concerned, PROVIDENCE SAINT JOSEPH was licensed to do business in, and was at all times herein alleged doing business in the County of Los Angeles, State of California.

3. Defendant GUIDANT CORPORATION is an Indiana corporation, with its principal place of business at 111 Monument Circle, 29th Floor, Indianapolis, Indiana. GUIDANT CORPORATION develops technology to treat conditions such as heart disease, neurological disorders, and vascular illness. Guidant's CRM Division is the division that develops, researches, advertises, promotes, markets, and sells all of Guidant's ICDs and pacemakers, which are marketed under a variety of trade names, with multiple models and serial numbers pertinent to each device. CRM Division's operations are principally conducted out of its facilities at 4100 Hamline Avenue North, St. Paul, Minnesota.

4. GUIDANT CORPORATION sells its ICDs and pacemakers through its wholly-owned subsidiary, Defendant GUIDANT SALES. GUIDANT SALES is an Indiana corporation, with its principal place of business at 111 Monument Circle in Indianapolis, Indiana.

5. Defendant CPI, a Minnesota corporation, developed Guidant's ICDs and pacemakers. CPI was merged into Guidant in or about September 1994, and is now a wholly-owned subsidiary of Guidant Corporation, with headquarters at 4100 Hamline Ave. North, St. Paul, Minnesota.

6. Defendant BOSTON SCIENTIFIC describes itself as a worldwide developer, manufacturer, and marketer of medical devices, whose products are used in a broad range of interventional medical specialties with reported revenue of $6.3 billion in 2005. BOSTON

SCIENTIFIC is incorporated in the State of Delaware with its principal executive office located in Natick, Massachusetts. In January 2006, BOSTON SCIENTIFIC entered into an agreement to acquire GUIDANT CORPORATION and its subsidiaries for approximately $27 billion. With final approval of that merger, BOSTON SCIENTIFIC is the successor in interest to Guidant and, directly or indirectly, has assumed Guidant's liabilities in this litigation. BOSTON SCIENTIFIC together with the other Guidant entities referenced above, will collectively be referred to throughout this complaint as GUIDANT and/or the Guidant defendants.

7. The Guidant defendants business units present themselves under the "Guidant" corporate banner to the general public, including to the Food and Drug Administration ("FDA"), physicians, and individuals. As the Independent Panel that reviewed Guidant Corp.'s device surveillance and disclosure policies concluded, "the public views Guidant Corporation as a single entity, rather than a group of individual businesses." Independent Panel Report at 16. Guidant Corp. promotes such a view by, among other things, including the Guidant logo on all device marketing materials.

8. Guidant Corp.'s business units have their own officers but are also tied together at the corporate level by a structure by which Guidant Corp. oversees the business units, including through the Guidant Management Committee.

9. The products of Guidant Corp.'s CRM Division include ICDs, pacemakers, and lead systems. ICDs are implanted medical devices used to detect and treat abnormally fast and irregular heart rhythms, each of which can stop or hinder the heart from pumping blood effectively throughout the body and can result in sudden cardiac death. Pacemakers are medical devices used to detect and treat abnormally slow heart rhythms.

10. Guidant holds itself out as "the world leader in the design and development of cardiovascular medical products." Guidant Corp., Corporate Overview, http://www.Guidant.com/about_us.shtml (last visited April 11, 2006). ICDs have been Guidant Corp.'s

fastest growing product for at least the last three years. The first ICD was placed on the market in 1985 by CPI, now wholly-owned by Guidant Corp. Between 2002 and 2004, Guidant Corp.'s revenues for sales of ICDs jumped 80% to $1.786 billion. In the past decade, implantable defibrillators and pacemakers have been one of the fastest growing groups of implantable medical devices and according to defendant GUIDANT CORPORATION'S Form 10-K filings, implantable defibrillators and pacemakers have been one of its highest revenue generating product groups for at least the last five years and is also the source of certain superlative promises, assurances and statements upon which the plaintiff and the plaintiff's treating physician relied in selecting the device at issue here. Some of the superlatives in GUIDANT CORPORATION'S annual reports include:

a. In its 2003 Annual Report, defendant GUIDANT CORPORATION characterized itself as a "pioneer in the development of implantable Defibrillator technologies ..." and that "the company's ongoing leadership is supported by remarkable capabilities in mechanical, electrical and computer engineering."

b. Further, touting its engineering capabilities, GUIDANT CORPORATION stated that "[s]uperior engineering spurred the launch of a new implantable Defibrillator in every quarter of the past year." Defendant GUIDANT CORPORATION described its manufacturing facilities as "exceptional."

c. In its 2003 Annual Report, GUIDANT CORPORATION stated "[e]xperienced technicians – supported by continued investment in state-of-the-art automated manufacturing equipment and expansion – have streamlined manufacturing processes to reduce costs, improve quality, increase [out]-put and shorten the product development and manufacturing cycle, speeding the delivery of lifesaving therapies to physicians and patients worldwide."

d. Emphasizing the company's focus on quality, GUIDANT CORPORATION stressed in its 2003 Annual Report that it has "an unrelenting focus on quality in everything it does." Defendant GUIDANT CORPORATION also publicly represented itself to be an open provider of

information to patients and physicians. In its 2003 Annual Report, the company stated that "information for patients, physicians, and the public is available around the clock through Guidant's dedicated customer and technical service representatives, as well as its comprehensive web site (www.guidant.com)."

e. Nowhere disclosed in any of these financial reports or in its marketing pieces outlined below, did the Guidant defendants reveal the truth, as laid out herein.

11. Defendant DOES 1 through 100 are individuals, corporations, partnerships or other business entities licensed to do business in the State of California, having their principal place of business in the State of California, and/or are residents of the State of California. Their true names or capacities are unknown to Plaintiff who, therefore, sues said defendants by such fictitious names. Plaintiff is informed and believes and thereon alleges that each of the fictitiously named defendants is legally responsible in some manner for the events and occurrences herein alleged, and that Plaintiff's injuries and damages as herein alleged were proximately caused by their conduct. Plaintiff will amend this complaint to allege the true names and capacities of DOES 1 through 100 when the same have been ascertained.

12. At all material times herein alleged, the GUIDANT defendants were engaged in the business of designing, manufacturing, and assembling implantable defibrillators and pacemakers, for the sale and use by members of the public, including Plaintiff, and as part of their business, defendants designed, manufactured, and assembled the implantable defibrillators and/or pacemakers referenced throughout this complaint and implanted into plaintiff.

13. At all times herein mentioned, the officers and/or directors of the corporate defendants named herein participated in, authorized and/or directed the production and promotion of the implantable defibrillators and/or pacemakers referenced herein when they knew or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and

thereby actively participated in the tortious conduct which resulted in the damages and physical injuries suffered by Plaintiff as described herein.

14. At all times herein mentioned, the defendants, and each of them, were the agents, servants, employees, partners, aiders and abettors, coconspirators and/or joint venturers of some or all of the other defendants herein and were at all times operating and acting within the course, scope, and authority of said agency, service, employment, partnership, conspiracy, and/or joint venture, and with the permission and consent of their co-defendants, and rendered substantial assistance and encouragement to the other defendants, knowing that their conduct constituted a breach of duty owed to Plaintiff. As such, each of said defendants is legally responsible for the actions of the other.

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

16. Plaintiff, GUSTAVO COVARRUBIAS BARRIGA had a defective Guidant ICD or pacemaker surgically paced in Plaintiff's body on or about April 12, 2002. Prior to the implant, Plaintiff was not advised or informed by defendants or any other person that the Guidant product implanted in Plaintiff's body possessed any defect or was susceptible to malfunction and/or failure and plaintiff did not learn of such potentiality until after becoming aware of the recalls and special advisories from Guidant that were published from between June 17, 2005 and June 23, 2006 and which are outlined in paragraph 31 below. Interestingly, these special advisories began about 3 weeks after defendant GUIDANT CORPORATION'S Vice President/Chief Medical and Technology Officer sold 23,300 shares of stock in the company for $1.71 million on May 17, 2005 and another 22,667 shares for

$1.68 million on May 23, 2005.

17. On or about November 29, 2005, Plaintiff's defective implant was replaced because of the Guidant Defendants' recall and the risk of malfunction and failure, which are described in more detail below.

18. Without Plaintiff's consent, and upon information and belief, a non-medical representative of the Guidant defendants, was present in the operating room during the implant and/or explantation of the device, in violation of plaintiff's privacy rights.

II. OVERVIEW OF CARDIAC RHYTHM MANAGEMENT IMPLANTABLE DEVICES

19. Cardiovascular disease is the leading cause of death for both men and women in the United States. Implantable devices for cardiac rhythm management have become an integral part of cardiovascular therapy. Implantable pacemakers for individuals with bradycardia (a slow heartbeat) were introduced more than 40 years ago, and the first ICD was implanted in 1980. (As used hereinafter, the term "Implantable Device" will refer to pacemakers and/or ICDs manufactured and sold by Defendants.) Thereafter, specialized pacemakers called cardiac resynchronization devices that improve the mechanical function of the heart were introduced and combined with existing ICD technology. Today, Implantable Devices are also commonly used for treatment of arrhythmia (an irregular heartbeat).

20. There has been explosive growth in ICD use. There are now, in just the United States, well over one million individuals living with an implanted cardiac rhythm device and this number is increasing rapidly. In 2005, approximately 200,000 people in the United States were implanted with ICDs.

21. The ICDs designed, manufactured and distributed into the stream of commerce by Guidant consist of three components: (1) a small rectangular generator, approximately two inches wide, which is implanted under the skin just below the collarbone; (2) insulated wires – or leads – which are

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attached to the generator and threaded through a vein to the heart, to carry the electric current from the generator; and (3) two electrodes, located at the tip of each lead, which deliver an electric shock to the heart.

22. The purpose of the ICD is to correct abnormal heart rhythm. The ICD can generate a series of precisely timed, low-intensity, electrical pulses to reset the heart to normal rhythm when the heart beats faster than normal (tachycardia); or the ICD can deliver sudden shocks to the heart to stop potentially fatal heart quivering (ventricular fibrillation). In addition, the ICD may be programmed as a pacemaker to send small electric signals if the heart beats too slowly (bradycardia).

23. Implantable CRT-D devices are medical devices that treat heart failure by helping the lower chamber (ventricles) pump synchronously with the upper chambers (atria), while preventing the heart from beating too slowly (bradycardia) and shocking or "over-drive pacing" of heartbeat rhythms that are too fast (a process by which the CRT-D is paced briefly at a rhythm faster than the desired rhythm in order to recapture control of the heartbeat).

24. All ICDs function as both pacemakers and defibrillators. The ICD can detect and correct both fast and slow heart rates. The ICD corrects the slow rates and can "over-drive pace" rapid rates and it also can administer shocks to treat ventricular tachycardia and ventricular fibrillation.

25. ICDs are used in individuals, like Plaintiffs, who have arrhythmias or irregular heartbeats that are considered life-threatening. These can include individuals with ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat) that is poorly controlled by medication, or significant thickening of the heart muscle resulting in arrhythmia. Such conditions can result in the loss of consciousness or death, unless the affected individual receives therapy from an appropriate device to put the heart back into a normal cardiac rhythm. Pacemakers are used in individuals, like Plaintiffs, who have bradycardia that is uncontrolled by medicine alone.

26. If an implanted ICD operates properly, it can save an individual's life. If it fails to operate properly, the individual could die within minutes.

27. Since 1958, pacemakers have been sold for implantation in individuals who have had certain spontaneous and/or inducible life-threatening arrhythmias, bradycardia, heart block, and congestive heart failure and those who are at high risk of developing bradycardia, heart block, or arrhythmias. Pacemakers are used to manage disorders that disrupt the heart's normal electrical conduction system.

28. Pacemakers are designed to be implanted under the skin of the chest wall. The device's power source (pulse generator) is implanted in a pouch formed under the collarbone, just under the skin, usually on the upper left chest. Wires, called leads, are inserted through a blood vessel and attached directly into the heart. These wires, which are connected to the pacemaker or pulse generator, are capable of both sensing a problematic heart rate and stimulating a more appropriate heart rate.

29. Some individuals are very dependent on pacemakers to maintain an adequate heart rate, and therefore, cardiac output. For these individuals, failure of the cardiac pacemaker to provide pacing can cause sudden faintness, or loss of consciousness, and can result in death.

30. At all times relevant, Guidant misrepresented the safety of its ICDs and pacemakers and negligently manufactured, marketed, advertised, promoted, sold, and distributed those ICDs and pacemakers as safe devices to be used for treatment of individuals with prior myocardial infarction, arrhythmias, and individuals who are at high risk for developing such arrhythmias.

III. IDENTIFICATION OF THE DEVICES AT ISSUE

31. From between 1998 and the present, the Guidant defendants have knowingly marketed defective devices without disclosing the true risks inherent in their devices, until they were forced to do beginning mid 2005 to the present. A list of the notices, advisories, recalls sent from the Guidant defendants, by device, model number, date of the notice of defect and the identified defect is identified below:

Device Name	Model No.	Type	Date of Guidant/FDA Notice/Alert/Release	Problem
Pulsar	470	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Meridian	476	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	481	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Insignia AVT SSI	482	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia AVT SSI	482	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra SSI	484	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra SSI	484	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra SSI	485	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra SSI	485	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Pulsar	870	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Insignia AVT VDD	882	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia AVT VDD	882	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Pulsar	972	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Meridian	976	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	981	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Insignia AVT DDD	982	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22

Insignia AVT VDD	982	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra DDD	985	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra DDD	985	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra DDD	986	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra DDD	986	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Pulsar Max	1170	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Pulsar Max	1171	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Pulsar	1172	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery	1174	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery	1175	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Meridian	1176	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Pulsar Max II	1180	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Pulsar Max II	1181	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	1184	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	1186	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	1187	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Insignia Ultra SR	1190	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Ultra SR	1190	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia AVT SR	1192	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia AVT SR	1192	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor

Insignia Plus SR	1194	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Plus SR	1194	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra SR	1195	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra SR	1195	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra SR	1198	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra SR	1198	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Contak TR	1241	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Pulsar Max	1270	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Pulsar	1272	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery	1273	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery	1274	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery	1275	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Meridian	1276	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Pulsar Max II	1280	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	1283	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	1284	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	1285	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Discovery II	1286	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Insignia Ultra DR	1290	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Ultra DR	1290	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor

Insignia Ultra DR	1291	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Ultra DR	1291	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia AVT DR	1292	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia AVT DR	1292	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra DR	1294	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra DR	1294	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra DR	1295	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra DR	1295	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Entra DR	1296	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra DR	1296	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Plus DR	1297	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Entra DR	1297	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Insignia Plus DR	1298	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Insignia Plus DR	1298	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Entra SSI	1325	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22

Nexus Entra SSI	1325	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Entra SSI	1326	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra SSI	1326	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus AVT SSI	1328	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus AVT SSI	1328	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Intelis II	1349	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Virtus Plus II	1380	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Intelis II	1384	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Intelis II	1385	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Nexus Ultra SR	1390	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Ultra SR	1390	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus AVT SR	1392	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus AVT SR	1392	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Plus SR	1394	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Plus SR	1394	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Entra SR	1395	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra SR	1395	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor

Nexus Entra SR	1398	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra SR	1398	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Entra DDD	1425	Pacemaker	9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra DDD	1426	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra DDD	1426	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus AVT VDD	1428	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus AVT VDD	1428	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus AVT DDD	1432	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus AVT DDD	1432	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Entra DR	1466	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra DR	1466	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Plus DR	1467	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Plus DR	1467	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Plus DR	1468	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Plus DR	1468	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor

Virtus Plus II	1480	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Intelis II	1483	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Intelis II	1484	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Intelis II	1485	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Nexus Ultra DR	1490	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Ultra DR	1490	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Ultra DR	1491	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Ultra DR	1491	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus AVT DR	1492	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus AVT DR	1492	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Entra DR	1494	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra DR	1494	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Nexus Entra DR	1495	Pacemaker	(1) 9/22/2005	(1) failure mode caused by foreign material in crystal timing component; (2) another failure mode w/ root cause unknown a/o 9/22
Nexus Entra DR	1495	Pacemaker	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Intelis II	1499	Pacemaker	(1) 7/18/2005, (2) 1/21/2006	degradation of hermetic sealing component
Ventak Prizm 2 VR	1860	ICD	6/26/2006	issue w/ low voltage capacitor
Ventak Prizm 2 DR	1861	ICD	(1) 5/23/05, 5/25/05, 6/17/05;	(1) wire insulator deterioration/short circuit
Ventak Prizm 2 DR	1861	ICD	(2) 6/16/05	(2) PEEK insulation material issue
Ventak Prizm 2 DR	1861	ICD	(3) 6/23/2006	issue w/ low voltage capacitor

Vitality	1870	ICD	6/23/2006	issue w/ low voltage capacitor
Vitality	1871	ICD	6/23/2006	issue w/ low voltage capacitor
Ventak Prizm AVT	1900	ICD	6/17/2005	random memory error/latching
Vitality AVT	A135	ICD	6/17/2005	random memory error/latching
Vitality AVT	A155	ICD	(1) 6/17/2005	(1) random memory error/latching
Vitality AVT	A155	ICD	(2) 5/12/06	(2) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal TR	H120	CRT-D	6/23/2006	issue w/ low voltage capacitor
Contak Renewal TR	H125	CRT-D	6/23/2006	issue w/ low voltage capacitor
Contak Renewal	H135	CRT-D	6/17/2005	wire insulator deterioration/short circuit
Contak Renewal TR 2	H140	CRT-D	6/23/2006	issue w/ low voltage capacitor
Contak Renewal TR 2	H145	CRT-D	6/23/2006	issue w/ low voltage capacitor
Contak Renewal 2	H155	CRT-D	6/17/2005	wire insulator deterioration/short circuit
Contak Renewal 3	H170	CRT-D	(1) 6/23/05, 8/1/05	(1) magnetic switch sticking in closed position
Contak Renewal 3	H170	CRT-D	(2) 5/10/06	(2) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 3	H170	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 3	H170	CRT-D	(4) 5/16/06	(4) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal 3	H170	CRT-D	(5) 5/31/06	(5) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Contak Renewal 3	H173	CRT-D	(1) 6/23/05, 8/1/05	(1) magnetic switch sticking in closed position
Contak Renewal 3	H173	CRT-D	(2) 5/12/06	(2) malfunction associated with subpectoral implantation with serial # facing the ribs

Contak Renewal 3	H173	CRT-D	(3) 5/16/06	(3) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal 3	H175	CRT-D	(1) 6/23/05, 8/1/05	(1) magnetic switch sticking in closed position
Contak Renewal 3	H175	CRT-D	(2) 5/10/06	(2) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 3	H175	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 3	H175	CRT-D	(4) 5/16/06	(4) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal 3	H175	CRT-D	(5) 5/31/06	(5) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Contak Renewal 3 HE	H177	CRT-D	(1) 6/16/05	(1) PEEK insulation material issue
Contak Renewal 3 HE	H177	CRT-D	(2) 6/23/05	(2) magnetic switch sticking in closed position
Contak Renewal 3 HE	H177	CRT-D	(3) 5/10/06	(3) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 3 HE	H177	CRT-D	(4) 5/12/06	(4) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 3 HE	H177	CRT-D	(5) 5/31/06	(5) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Contak Renewal 3 HE	H179	CRT-D	(1) 6/23/05	(1) magnetic switch sticking in closed position
Contak Renewal 3 HE	H179	CRT-D	(2) 5/10/06	(2) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 3 HE	H179	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs

Contak Renewal 3 HE	H179	CRT-D	(4) 5/31/06	(4) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Contak Renewal 4	H190	CRT-D	(1) 6/23/2005	(1) magnetic switch sticking in closed position
Contak Renewal 4	H190	CRT-D	(2) 5/10/06	(2) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 4	H190	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4	H190	CRT-D	(4) 5/16/06	(4) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal 4	H190	CRT-D	(5) 5/31/06	(5) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Contak Renewal 4	H195	CRT-D	(1) 6/23/2005	(1) magnetic switch sticking in closed position
Contak Renewal 4	H195	CRT-D	(2) 5/10/06	(2) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 4	H195	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4	H195	CRT-D	(4) 5/16/06	(4) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal 4	H195	CRT-D	(5) 5/31/06	(5) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Contak Renewal 4 HE	H197	CRT-D	(1) 6/23/2005	(1) magnetic switch sticking in closed position
Contak Renewal 4 HE	H197	CRT-D	(2) 5/10/06	(2) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 4 HE	H197	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4 HE	H199	CRT-D	(1) 6/23/2005	(1) magnetic switch sticking in closed position

Contak Renewal 4 HE	H199	CRT-D	(2) 5/12/06	(2) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4 HE	H199	CRT-D	(3) 5/31/06	(3) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Contak Renewal 3 RF	H210	CRT-D	5/24/06	Pre-implant issue: Lower than expected battery voltage prior to implant
Contak Renewal 3 RF	H215	CRT-D	5/24/06	Pre-implant issue: Lower than expected battery voltage prior to implant
Contak Renewal 3 RF HE	H217	CRT-D	5/24/06	Pre-implant issue: Lower than expected battery voltage prior to implant
Contak Renewal 3 RF HE	H219	CRT-D	5/24/06	Pre-implant issue: Lower than expected battery voltage prior to implant
Contak Renewal 4 RF	H230	CRT-D	(1) 6/23/05, 8/1/05	(1) magnetic switch sticking in closed position
Contak Renewal 4 RF	H230	CRT-D	(2) 5/24/06	(2) Pre-implant issue: Lower than expected battery voltage prior to implant
Contak Renewal 4 RF	H235	CRT-D	(1) 6/23/05, 8/1/05	(1) magnetic switch sticking in closed position
Contak Renewal 4 RF	H235	CRT-D	(2) 5/24/06	(2) Pre-implant issue: Lower than expected battery voltage prior to implant
Contak Renewal 4 RF HE	H239	CRT-D	(1) 6/23/2005	(1) magnetic switch sticking in closed position
Contak Renewal 4 RF HE	H239	CRT-D	(2) 5/24/06	(2) Pre-implant issue: Lower than expected battery voltage prior to implant
Contak Renewal 3 AVT	M150	CRT-D	(1) 6/17/05	(1) random memory error/latching
Contak Renewal 3 AVT	M150	CRT-D	(2) 6/23/05, 8/1/05	(2) magnetic switch sticking in closed position
Contak Renewal 3 AVT	M150	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 3 AVT	M155	CRT-D	(1) 6/17/05	(1) random memory error/latching
Contak Renewal 3 AVT	M155	CRT-D	(2) 6/23/05, 8/1/05	(2) magnetic switch sticking in closed position
Contak Renewal 3 AVT	M155	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 3 AVT HE	M157	CRT-D	(1) 6/7/05	(1) random memory error/latching
Contak Renewal 3 AVT HE	M157	CRT-D	(2) 6/23/05	(2) magnetic switch sticking in closed position

Contak Renewal 3 AVT HE	M157	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 3 AVT HE	M159	CRT-D	(1) 6/7/05	(1) random memory error/latching
Contak Renewal 3 AVT HE	M159	CRT-D	(2) 6/23/05	(2) magnetic switch sticking in closed position
Contak Renewal 3 AVT HE	M159	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4 AVT	M170	CRT-D	(1) 6/17/05	(1) random memory error/latching
Contak Renewal 4 AVT	M170	CRT-D	(2) 6/23/05, 8/1/05	(2) magnetic switch sticking in closed position
Contak Renewal 4 AVT	M170	CRT-D	(3) 5/10/06	(3) cracked layer of insulation in a flexible hybrid circuit
Contak Renewal 4 AVT	M170	CRT-D	(4) 5/12/06	(4) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4 AVT	M170	CRT-D	(5) 5/16/06	(5) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal 4 AVT	M175	CRT-D	(1) 6/17/05	(1) random memory error/latching
Contak Renewal 4 AVT	M175	CRT-D	(2) 6/23/05, 8/1/05	(2) magnetic switch sticking in closed position
Contak Renewal 4 AVT	M175	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4 AVT	M175	CRT-D	(4) 5/16/06	(4) capacitor defect (single supplier) resulting in premature battery depletion
Contak Renewal 4 AVT HE	M177	CRT-D	(1) 6/17/05	(1) random memory error/latching
Contak Renewal 4 AVT HE	M177	CRT-D	(2) 6/23/05	(2) magnetic switch sticking in closed position
Contak Renewal 4 AVT HE	M177	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Contak Renewal 4 AVT HE	M179	CRT-D	(1) 6/17/05	(1) random memory error/latching
Contak Renewal 4 AVT HE	M179	CRT-D	(2) 6/23/05	(2) magnetic switch sticking in closed position
Contak Renewal 4 AVT HE	M179	CRT-D	(3) 5/12/06	(3) malfunction associated with subpectoral implantation with serial # facing the ribs
Vitality HE	T180	ICD	(1) 5/10/06	(1) cracked layer of insulation in a flexible hybrid circuit
Vitality HE	T180	ICD	(2) 5/12/06	(2) malfunction associated with subpectoral implantation with serial # facing the ribs

Vitality DS	T125	ICD	(1) 5/12/06	(1) capacitor defect (single supplier) resulting in premature battery depletion
Vitality DS	T125	ICD	(2) 5/31/06	(2) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Vitality DS	T125	ICD	(3) 6/23/2006	(3) issue w/ low voltage capacitor
Vitality DS	T127	ICD	6/23/2006	issue w/ low voltage capacitor
Vitality DS VR	T135	ICD	(1) 5/12/06	(1) capacitor defect (single supplier) resulting in premature battery depletion
Vitality DS VR	T135	ICD	(2) 6/23/2006	(2) issue w/ low voltage capacitor
Vitality 2 DR	T165	ICD	(1) 5/12/06	(1) capacitor defect (single supplier) resulting in premature battery depletion
Vitality 2 DR	T165	ICD	(2) 5/31/06	(2) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Vitality 2 DR	T165	ICD	(3) 6/23/2006	(3) issue w/ low voltage capacitor
Vitality 2 DR	T167	ICD	6/23/2006	issue w/ low voltage capacitor
Vitality 2 DR VR	T175	ICD	(1) 5/12/06	(1) capacitor defect (single supplier) resulting in premature battery depletion
Vitality 2 DR VR	T175	ICD	(2) 5/31/06	(2) battery welds performed at settings outside of typical manufacturing specifications at the supplier
Vitality 2 DR VR	T175	ICD	(3) 6/23/2006	(3) issue w/ low voltage capacitor
Vitality 2 DR VR	T177	ICD	6/23/2006	issue w/ low voltage capacitor

32. On May 15, 2006, Boston Scientific published an updated CRM Product Performance Report, which identified the number of known, confirmed malfunctions and premature battery depletions with respect to some of the devices referenced above. Again, not all of the devices listed above were included in this report and in the chart below, separated by device, is a list of approximately 2000 units with a known defect in the United States and over 2600 units worldwide, that have had

identified malfunctions and premature battery depletions with certain of Guidant ICDs and/or pacemakers:

Trade Name of Device	Model Numbers	Approval Date	US Confirmed Malfunction	US Unconfirmed Premature Battery Depletion	WW Confirmed Malfunction
CRT-D					
Contak Renewal 3 RF HE	H217 H219	Feb-05	0	0	0
Contak Renewal 3 RF	H210 H215	Feb-05	1	0	1
Contak Renewal 3 HE	H177 H179	Jun-03	21	7	21
Contak Renewal 3	H170 H175	Jun-03	40	10	40
Contak Renewal	H135	Dec-02	45	43	65
Contak Renewal TR	H120 H125	Jan-04	0	2	0
ICDs					
Vitality DR HE	T180	May-05	0	0	0
Vitality 2 EL DR	T167	Mar-04	2	0	4
Vitality 2 DR	T165	Mar-04	7	2	7
Vitality 2 EL VR	T177	Mar-04	3	0	3
Vitality 2 VR	T175	Mar-04	3	3	3
Vitality AVT A155	A155	Oct-03	36	4	36
Vitality AVT A135	A135	Mar-03	27	19	32
Vitality DS DR	T125	Jul-03	8	3	8
Vitality DS VR	T135	Jul-03	8	3	8
Vitality EL	T127	Jul-03	4	0	4
Ventak Prizm 2 DR	1861	Aug-00	148	22	188
Ventak Prizm 2 VR	1860	Aug-00	52	12	71
Ventak Prizm DR HE	1853 1858	Aug-00	74	53	106
Ventak Prizm VR HE	1852 1857	Aug-00	30	8	49
Ventak Prizm DR	1851 1856	Jan-00	259	47	382
Ventak Prizm VR	1850 1855	Jan-00	73	12	139
Pacemakers					
Insignia Ultra SR	1190	Nov-03	0	0	0
Insignia Ultra DR	1290	Nov-03	2	1	7
Insignia Ultra DR	1291	Nov-03	1	0	4
Insignia Entra SR	1195 1198	Mar-02	0	2	2
Insignia Entra DR	1296	Mar-02	3	3	5

Insignia Entra DR	1294 1295	Mar-02	6	0	9
Insignia Plus SR	1194	Mar-02	7	1	9
Insignia Plus DR	1297	Mar-02	3	2	5
Insignia Plus DR	1298	Mar-02	33	40	40
Pulsar Max II SR	1180	May-01	1	4	2
Pulsar Max II SR	1181	May-01	0	0	1
Pulsar Max II DR	1280	May-01	12	12	1
Discovery II SR	1184	Mar-00	2	3	2
Discovery II SR	1186 1187	Mar-00	1	1	1
Discovery II DR	1283	Mar-00	16	40	19
Discovery II DR	1284 1286	Mar-00	6	5	13
Pulsar Max SR	1170	Jun-99	6	3	10
Pulsar Max SR	1171	Jun-99	5	0	8
Pulsar Max DR	1270	Jun-99	77	39	107
Pulsar DR	1272	Jun-99	1	0	2
Discovery SR	1174	Apr-98	78	8	131
Discovery SR	1175	Apr-98	1	0	3
Discovery DR	1273	Apr-98	145	67	156
Discovery DR	1274 1275	Apr-98	114	14	181
Meridian DDD	976	Apr-98	4	1	48
Meridian SSI	476	Apr-98	0	0	39
Meridian SR	1176	Apr-98	18	10	47
Meridian DR	1276	Apr-98	34	12	55
TOTALS			1417	518	2074

33. As part of the conditions of approval for the devices listed above, Defendants must ensure that no changes be made to the Device that would affect its safety or effectiveness without submission of a Pre-Market Approval ("PMA") supplement for review and approval, and that a PMA

supplement must be submitted when a device failure necessitates a labeling, manufacturing, or device modification. Violation of such conditions voids their approval.

34. The removal of Devices from the market and other corrective actions taken by Guidant have been classified as Class I or Class II recalls under federal regulations – the highest levels of such recalls.

35. Under federal regulation "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. § 7.3(g) (2006).

36. The classification of a recall as Class I, II, or III "indicate[s] the relative degree of health hazard presented by the product being recalled." *Id.* § 7.3(m). "Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." *Id.* § 7.3(m)(1). "Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." *Id.* § 7.3(m)(2).

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

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

39. Manufacturers are required to comply with FDA regulation of medical devices, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or

contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. § 360i.

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

41. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. *See* 21 C.F.R. § 803.52.

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

43. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the

corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. § 806.10.

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

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

46. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification." Conditions of Approval at 1, attached to FDA Approval Letter from Daniel G. Schultz, Deputy Director for Clinical Policy, FDA, to Kaye

Anderson, Senior U.S. Regulatory Affairs Associate, Guidant Corporation (July 18, 2002); *see* 21 C.F.R. § 814.39.

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

IV. HISTORY OF THE DEVICES

A. Summary

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

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

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

the potentially fatal defects that their investigation uncovered, Mr. Oukrop's physicians brought the issues to the attention of the New York Times.

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

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

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

54. While Guidant had provided some information to the FDA that information was incomplete and misleading and did not adequately disclose the Device defects. Guidant's flawed disclosures did not comply with FDA regulations and violated the conditions of approval for the Devices.

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

Plaintiffs, the medical community, regulators, and the public from making informed choices about the use of the Devices.

B. Ventak Prizm ICDs

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

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

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

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

60. On July 18, 2002, under supplemental approval, the FDA expanded the approved indication of all the Ventak Prizm ICDs for the prophylactic treatment of individuals with prior myocardial infarctions and an ejection fraction of 30% or more.

61. According to Guidant's May 25, 2005 press release, approximately 24,000 Ventak Prizm 2 DR 1861 ICDs are currently implanted in individuals worldwide. *See* Press Release, Guidant Corp.,

Guidant Notifies Physicians Regarding Ventak 1861 Prizm 2 DR Implantable Defibrillator (May 25, 2005) ("May 25 Guidant Press Release"). Guidant later informed the New York Times that as many as 37,000 defective Ventak Prizm 2 DR 1861 devices were implanted. *See* Barry Meier, *Flawed Implants: Disclosure and Delay*, N.Y. Times, June 14, 2005, at C.

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

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

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

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

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

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

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

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

70. A June 2, 2005 New York Times article revealed that after April 2002, and after Guidant had clear and definite knowledge of the defect, nine defective ICDs (manufactured before April 2002 and therefore lacking the modifications intended to increase the spacing between the feedthru wire and the backfill tube) were implanted in individuals at Abbott Northwestern Hospital alone. According to a

May 24, 2005 New York Times article, in three cases, the Ventak Prizm devices failed to work when doctors intentionally induced abnormal heart rhythms during checkups, forcing the doctors to rescue the individuals with external defibrillator paddles of the type used in emergency rooms.

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

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

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

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

75. Physicians at the Minneapolis Heart Institute Foundation searched the FDA database for adverse events involving medical devices and identified several other reports involving the Ventak Prizm 2 DR 1861, where the device short circuited and failed in the same manner as their patient's device. They then confronted Guidant officials on May 12, 2005 regarding the recurring electrical short-circuiting defect they had discovered in the Ventak Prizm 2 DR 1861 and reminded Guidant of its obligations to notify patients and physicians of the defect. Guidant officials, however, refused and

maintained instead that there was no reason to notify physicians, patients, or the public of the defect in their product.

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

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

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

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

80. Guidant did not file the required PMA Supplement with respect to the 2002 manufacturing changes to the Ventak Prizm 2 DR 1861. Although Guidant filed a nonpublic annual report with the FDA in August 2003, Guidant's disclosure did not reveal that the Ventak Prizm 2 DR 1861 ICDs might be subject to a potentially fatal failure or that Guidant's disclosure was incomplete,

misleading, and improper, and was intended to hide the known defect in existing Ventak Prizm 1861s from Plaintiffs and others who were implanted with the device.

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

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

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

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

circuitry for individuals implanted with a Ventak Prizm 2 DR 1861, although such testing will not exclude the likelihood the device might later fail because of the defect.

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

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

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

C. Contak Renewal 1 and 2

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

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

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

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

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

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

94. Guidant stated that there is no way of predicting whether "any particular device will fail." *Id.* at 3. According to the June 17 Contak Renewal 1 & 2 Letter, fifteen reports of the

malfunction had been confirmed, at least, one of which was fatal, and approximately 16,000 of the devices had been implanted worldwide. *See id.* at 1.

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

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

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

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

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

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

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

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

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

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

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

D. Contak Renewal 3 and 4

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

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

108. Guidant has recommended that physicians cease implantation of the Contak Renewal 3 & 4 and use a different product that contains a new switch component. As to currently implanted Contak Renewal 3 & 4 devices, Guidant has recommended that individuals seek medical intervention to switch the magnet off and seek immediate medical attention if the device is emitting audible tones. In June 2005, Guidant promised, but has not delivered as of it latest Product Performance Report issued in

2006, a programmer software application to correct the problem. The FDA has classified Guidant's actions with respect to Contak Renewal 3 & 4 as a Class II recall, which is defined as a product malfunction that may cause temporary or medically reversible adverse heath consequences.

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

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

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

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

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

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

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

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

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

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

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

118. Guidant manufactures a family of pacemakers that includes the Pulsar Max, Pulsar, Discovery, Meridian, Pulsar Max II, Discovery II, Contak TR, Virtus Plus II, and Intelis II devices (hereafter referred to as "Guidant Pacemakers"). As a result of defects in manufacturing, Guidant