# EXHIBIT B1

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ASSIGNED TO
JUDGE PAUL L. BEEMAN
FOR ALL PURPOSES

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF SOLANO

BY FAX

CLIFFORD HOSLER and DALE PATTON

Plaintiffs,

v.

GUIDANT CORPORATION; GUIDANT SALES CORPORATION; CARDIAC PACEMAKERS, INC.; BOSTON SCIENTIFIC CORPORATION; SUTTER SOLANO MEDICAL CENTER; NORTHBAY HEALTHCARE CORPORATION; and DOES 1 through 100, inclusive,

Defendants.

Case No.: FCS028064

**COMPLAINT FOR DAMAGES**

Plaintiffs, CLIFFORD HOSLER and DALE PATTON, by and through their attorneys, Gillin, Jacobson, Ellis & Larsen, for causes of action against Defendants, and each of them, allege the following:

**PRELIMINARY ALLEGATIONS COMMON TO ALL CAUSES OF ACTION**

**I. THE PARTIES AND VENUE ALLEGATIONS**

1. Plaintiff, CLIFFORD HOSLER, is a resident of the State of California, County of Solano. The County of Solano was the County where the products complained of herein were actually used. At all times herein mentioned, the County of Solano was the site of acts,

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**I. THE PARTIES AND VENUE ALLEGATIONS**

1. Plaintiff, CLIFFORD HOSLER, is a resident of the State of California, County of Solano. The County of Solano was the County where the products complained of herein were actually used. At all times herein mentioned, the County of Solano 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. Plaintiff, DALE PATTON, is a resident of the State of California, County of Solano. The County of Solano was the County where the products complained of herein were actually used. At all times herein mentioned, the County of Solano was the site of acts, negligence, and wrongful and tortious conduct that resulted in the injuries and damages complained of as set forth herein.

3. Defendant Sutter Solano Medical Center ("SUTTER SOLANO") 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 Solano. Plaintiff is informed and believes and thereon alleges, that at all times herein concerned, Defendant SUTTER SOLANO was licensed to do business in, and was at all times herein alleged doing business in the County of Solano, State of California. Plaintiff is informed and believes and thereon alleges that at all times herein concerned, Defendant SUTTER SOLANO owned and operated Sutter Medical Center, located at 300 Hospital Drive in Vallejo, California.

4. Defendant Northbay Healthcare Corporation ("NORTHBAY") 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 Solano. Plaintiff is informed and believes and thereon alleges, that at all times herein concerned, Defendant NORTHBAY was licensed to do business in, and was at all times herein alleged doing business in the County of Solano, State of California. Plaintiff is informed and believes and thereon alleges that at all times herein concerned, Defendant NORTHBAY owned and operated Northbay Medical Center, located at 1200 B. Gale Wilson Boulevard in Fairfield, California.

5. Defendant Guidant Corporation ("GUIDANT CORP.") is an Indiana corporation, with its principal place of business at 111 Monument Circle, 29th Floor, Indianapolis, Indiana. GUIDANT CORP. develops technology to treat conditions such as heart disease, neurological disorders, and vascular illness. GUIDANT CORP.'s CRM Division is the division that develops, researches, advertises, promotes, markets, and sells all of Guidant's implantable cardioverter

defibrillators ("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.

6. GUIDANT CORP. sells its ICDs and pacemakers through its wholly-owned subsidiary, Defendant Guidant Sales Corporation ("GUIDANT SALES"). GUIDANT SALES is an Indiana corporation, with its principal place of business at 111 Monument Circle in Indianapolis, Indiana.

7. Defendant Cardiac Pacemakers, Inc. ("CPI"), a Minnesota corporation, developed Guidant's ICDs and pacemakers. CPI was merged into GUIDANT CORP. in or about September 1994, and is now a wholly-owned subsidiary of GUIDANT CORP., with headquarters at 4100 Hamline Ave. North, St. Paul, Minnesota.

8. Defendant Boston Scientific Corporation ("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 CORP. and its subsidiaries for approximately $27 billion. With final approval of that merger, BOSTON SCIENTIFIC is the successor in interest to GUIDANT CORP. and, directly or indirectly, has assumed GUIDANT CORP.'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.

9. 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.

10. 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.

11. 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.

12. 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/about_us.shtml (last visited May 30, 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, ICDs and pacemakers have been one of the fastest growing groups of implantable medical devices and according to Defendant GUIDANT CORP.'s Form 10-K filings, ICDs 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 Plaintiffs and Plaintiffs' treating physicians relied in selecting the device at issue here. Some of the superlatives in GUIDANT CORP.'S annual reports include:

a. In its 2003 Annual Report, defendant GUIDANT CORP. 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 CORP. stated that "[s]uperior engineering spurred the launch of a new implantable Defibrillator in every quarter of the past year." Defendant GUIDANT CORP. described its manufacturing facilities as

"exceptional."

c. In its 2003 Annual Report, GUIDANT CORP. 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 CORP. stressed in its 2003 Annual Report that it has "an unrelenting focus on quality in everything it does." Defendant GUIDANT CORP. 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.

13. 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 Plaintiffs who, therefore, sue said defendants by such fictitious names. Plaintiffs are informed and believe and thereon allege that each of the fictitiously named defendants is legally responsible in some manner for the events and occurrences herein alleged, and that Plaintiffs' injuries and damages as herein alleged were proximately caused by their conduct. Plaintiffs will amend this complaint to allege the true names and capacities of DOES 1 through 100 when the same have been ascertained.

14. 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 Plaintiffs, and as part of their business, defendants designed, manufactured, and assembled the implantable

defibrillators and/or pacemakers referenced throughout this complaint and implanted into Plaintiffs.

15. 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 Plaintiffs as described herein.

16. 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 Plaintiffs. As such, each of said defendants is legally responsible for the actions of the other.

17. 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.

18. Plaintiff CLIFFORD HOSLER had a defective Guidant ICD or pacemaker surgically placed in his body on or about April 9, 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 May 15, 2006 and are outlined in paragraph 36 below. Interestingly, these special advisories began about 3 weeks after Defendant GUIDANT CORP.'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.

19. On or about August 15, 2005, Plaintiff CLIFFORD HOSLER'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.

20. Without Plaintiff CLIFFORD HOSLER'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.

21. Plaintiff DALE PATTON had a defective Guidant ICD or pacemaker surgically placed in his body on or about September 27, 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 May 15, 2006 and are outlined in paragraph 36 below. Interestingly, these special advisories began about 3 weeks after Defendant GUIDANT CORP.'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.

22. On or about June 28, 2005, Plaintiff DALE PATTON'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.

23. Without Plaintiff DALE PATTON'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

24. 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).

25. 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.

26. 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 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.

27. 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).

28. Implantable CRT-D devices are medical devices that treat heart failure by helping the lower chambers (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).

29. 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.

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. At all times relevant, Defendants 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. AN IDENTIFCATION OF THE DEVICES AT ISSUE

36. 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 |
|---|---|---|---|---|
| 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 AVT | 1900 | ICD | 6/17/2005 | random memory error/latching |
| Vitality 2 DR | T165 | ICD | 5/12/06 | capacity defect (single supplier) resulting in premature battery depletion |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Vitality 2 DR VR | T175 | ICD | 5/12/06 | capacity defect (single supplier) resulting in premature battery depletion |
| 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) capacity defect (single supplier) resulting in premature battery depletion |
| Vitality DS | T125 | ICD | 5/12/06 | capacity defect (single supplier) resulting in premature battery depletion |
| Vitality DS VR | T135 | ICD | 5/12/06 | capacity defect (single supplier) resulting in premature battery depletion |
| 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 |
| Contak Renewal | H135 | CRT-D | 6/17/2005 | wire insulator deterioration/short circuit |
| Contak Renewal 2 | H155 | CRT-D | 6/17/2005 | wire insulator deterioration/short circuit |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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) capacity defect (single supplier) resulting in premature battery depletion |
| 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) capacity 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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) capacity defect (single supplier) resulting in premature battery depletion |
| 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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 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 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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 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 | 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) capacity defect (single supplier) resulting in premature battery depletion |
| Contak Renewal 4 | H195 | CRT-D | (1) 6/23/2005 | (1) magnetic switch sticking in closed position |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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) capacity defect (single supplier) resulting in premature battery depletion |
| 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) capacity defect (single supplier) resulting in premature battery depletion |
| Contak Renewal 4 AVT | M175 | CRT-D | (1) 6/17/05 | (1) random memory error/latching |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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) capacity 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 |
| Contak Renewal 4 HE | H197 | CRT-D | (1) 6/23/2005 | (1) magnetic switch sticking in closed position |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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 TR | 1241 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery | 1174 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery | 1175 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery | 1273 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery | 1274 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery | 1275 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 481 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 981 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 1184 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 1186 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 1187 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 1283 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 1284 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Discovery II | 1285 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Discovery II | 1286 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Insignia AVT DDD | 982 | 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 |
| Insignia AVT DR | 1292 | 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 |
| Insignia AVT SR | 1192 | 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 |
| Insignia AVT SSI | 482 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Insignia AVT VDD | 882 | 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 |
| Insignia Entra DDD | 985 | 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 |
| Insignia Entra DDD | 986 | 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 |
| Insignia Entra DR | 1294 | 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 |
| Insignia Entra DR | 1295 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Insignia Entra DR | 1296 | 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 |
| Insignia Entra SR | 1195 | 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 |
| Insignia Entra SR | 1198 | 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 |
| Insignia Entra SSI | 484 | 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 |
| Insignia Entra SSI | 485 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Insignia Plus DR | 1297 | 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 |
| Insignia Plus DR | 1298 | 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 |
| Insignia Plus SR | 1194 | 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 |
| Insignia Ultra DR | 1290 | 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 |
| Insignia Ultra DR | 1291 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Insignia Ultra SR | 1190 | 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 |
| Intelis II | 1349 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Intelis II | 1384 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Intelis II | 1385 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Intelis II | 1483 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Intelis II | 1484 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Intelis II | 1485 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Intelis II | 1499 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Meridian | 476 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Meridian | 976 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Meridian | 1176 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Meridian | 1276 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Nexus AVT DDD | 1432 | 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 AVT DR | 1492 | 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 AVT SR | 1392 | 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 AVT SSI | 1328 | 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 AVT VDD | 1428 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| 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 | 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 | 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 | 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 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Nexus Entra SR | 1395 | 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 SR | 1398 | 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 SSI | 1325 | 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 SSI | 1326 | 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 Plus DR | 1467 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Nexus Plus DR | 1468 | 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 Plus SR | 1394 | 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 Ultra DR | 1490 | 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 Ultra DR | 1491 | 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 Ultra SR | 1390 | 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 |

| Device Name | Model No. | Type | Date of Guidant/FDA Notice/Alert/Release | Problem |
|---|---|---|---|---|
| Pulsar | 470 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar | 870 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar | 970 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar | 972 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar | 1172 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar | 1272 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar Max | 1170 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar Max | 1171 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar Max | 1270 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar Max II | 1180 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar Max II | 1181 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Pulsar Max II | 1280 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Virtus Plus II | 1380 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |
| Virtus Plus II | 1480 | Pacemaker | 7/18/2005, 1/21/2006 | degradation of hermetic sealing component |

37. 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; 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 Nos. | 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 |

| Trade Name of Device | Model Nos. | Approval Date | US Confirmed Malfunction | US Unconfirmed Premature Battery Depletion | WW Confirmed Malfunction |
|---|---|---|---|---|---|
| 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 | Mar-02 | 6 | 0 | 9 |

| Trade Name of Device | Model Nos. | Approval Date | US Confirmed Malfunction | US Unconfirmed Premature Battery Depletion | WW Confirmed Malfunction |
|---|---|---|---|---|---|
| | 1295 | | | | |
| 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<br>1187 | Mar-00 | 1 | 1 | 1 |
| Discovery II DR | 1283 | Mar-00 | 16 | 40 | 19 |
| Discovery II DR | 1284<br>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<br>1275 | Apr-98 | 114 | 14 | 181 |
| Meridian DDD | 976 | Apr-98 | 4 | 1 | 48 |

| Trade Name of Device | Model Nos. | Approval Date | US Confirmed Malfunction | US Unconfirmed Premature Battery Depletion | WW Confirmed Malfunction |
|---|---|---|---|---|---|
| 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** |

38. 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 is submitted when a device failure necessitates a labeling, manufacturing, or device modification. Violation of such conditions voids their approval.

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

40. 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).

41. 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).