UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Joseph D. Houlette, **Plaintiff,** **v.** **St. Jude Medical, Inc., and Pacesetter, Inc.,** **Defendants.**	Court File No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

I. INTRODUCTION

1. Plaintiff brings this Complaint against St. Jude Medical, Inc., and Pacesetter, Inc. (collectively referred to as "St. Jude" or "Defendants") for injuries caused by manufacturing defects in the St. Jude Riata and Riata ST Leads (hereinafter referred to as "Riata Leads" or "Leads"). Plaintiff alleges that he was implanted with a defective Riata Lead and suffered injury.

2. St. Jude manufactures a variety of medical devices to treat heart conditions including implantable cardiac defibrillators ("ICDs"). Wires called Leads, are attached to the ICD, then inserted through a major vein and attached directly to the muscle on the inside of the heart, thereby connecting the ICD to the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and correct any irregular rhythms.

3. St. Jude Medical introduced its Riata Leads into the U.S. Market beginning in 2002. Approximately 227,000 Riata leads have been sold worldwide since approved for marketing. 79,000 Riata Leads are estimated to remain active in the United States.

4. Recently, the Food and Drug Administration (FDA) issued a Class I Recall for the following Riata Lead model numbers:

Riata (8Fr): 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592; and Riata (7Fr): 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042 (collectively "Riata Leads").

II. PARTIES

A. Plaintiff

5. Plaintiff is a citizen and resident of the State of New Mexico.

6. Plaintiff was implanted with a Riata Lead Model #1581 on September 30, 2003. In April 2012, Plaintiff first learned of the recall of his Riata lead and the fact that his Riata lead was failing. On April 19, 2012, Plaintiff underwent invasive surgery to remove and replace the defective Riata Lead.

7. As a result of the defect in his Riata lead, Plaintiff has been injured and will continue to suffer physical, emotional, economic and other damage.

B. Defendant

8. Defendant St. Jude Medical, Inc. is a Minnesota Corporation that is headquartered in St. Paul, Minnesota at One St. Jude Medical Drive, St. Paul, Minnesota, 55117.

9. Defendant St. Jude Medical manufactures medical devices that are sold in more than 100 countries around the world and had net sales of over $5.6 billion in 2011.

10. Defendant Pacesetter, Inc. ("Pacesetter") is a Delaware corporation with its principle place of business at 15900 Valley View Court, in Slymar, California. Pacesetter, doing business as St. Jude Medical Cardiac Rhythm Management Division, develops, manufactures, and distributes cardiovascular and implantable neurostimulation medical devices, including the Riata and Riata ST leads at issue here. Pacesetter operates as a wholly owned subsidiary of St. Jude Medical, Inc. Prior to 1994, Pacesetter was known as Siemens Pacesetter, Inc.

11. Pacesetter also holds the trademark for Riata. Specifically, on September 07, 2001, Pacesetter filed a federal trademark registration. The United States Patent Trademark Office (USPTO) issued the RIATA trademark, serial number 76310892, to Pacesetter on November 5, 2002. The correspondent listed for RIATA is Steven M. Mitchell of Pacesetter, Inc., 15900 Valley View Court, Sylmar CA 91342. The RIATA trademark is filed in the category of Medical Instrument Products. At all relevant times, each of the Defendants and their directors and officers acted within the scope of their authority and on behalf of each other Defendant. During the relevant times, Defendants possessed a unity of interest between themselves and St. Jude Medical exercised control over its subsidiaries and affiliates. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

III. JURISDICTION AND VENUE

12. The Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332 insofar as the parties are citizens of different states and the amount in controversy in this matter exceeds Seventy-Five Thousand Dollars ($75,000), exclusive of interest and costs.

13. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391 (a)(2) because Defendants regularly solicited and engaged in business and other persistent courses of conduct and derived substantial revenues from goods used in the State of Minnesota. Defendants also hold offices in the State of Minnesota.

III. FACTUAL ALLEGATIONS

A. Brief History Of The Heart Devices

14. In 1980, termination of human arrhythmias with ICDs was reported in the New England Journal of Medicine. Thereafter, a number of devices were approved and manufactured to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms. ICDs include pacemakers as well as defibrillators. Pacemakers are used primarily to correct slow heart rates. Defibrillators detect and correct both fast and slow heart rates. Using the pacemaker and defibrillator function, an ICD can correct slow heart rates, pace rapid heart rates, and administer a shock to stop the heart and allow for a return to an appropriate rhythm.

15. Generally, leads act to conduct the electrical impulses between the heart and the ICD. Low voltage pacing therapy to treat slow heart rhythms is provided through pace-sense electrodes. High voltage shocks for defibrillation are provided through high

voltage conductors. Typically, high voltage leads are inserted through a major vessel and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can transmit an electric shock from the ICD to abort dangerous heart rhythms or pace the heart at a normal rhythm.

16. Any failure that compromises the ability of the lead to conduct electrical signals will result in a failure of the ICD to perform properly. Lead failures may include externalization of the conductors, abrasion, fractured wires, insulation loss, loss of ability to capture, changes in electrical characteristics in the ventricle chamber, abnormal lead impedance, sensing failure, and changes in tissue conductor interface.

B. <u>The Regulatory Approval Process Generally</u>

17. A pre-market approval application ("PMA") must be submitted to the FDA for any Class III medical device. *See* 21 U.S.C. 515(b); 21 C.F.R. §814.3(e). A PMA must contain certain information which is critical to the FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA and/or PMA Supplement application must provide:

a) proposed indications for use;

b) device description including the manufacturing process;

c) any marketing history;

d) summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e) methods used in manufacturing the device, including compliance with current good manufacturing practices; and

f) information relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the manufacturer from any source, including commercial marketing experience.

C. The Regulatory Approval Process Specific to the Riata Leads

18. On March 11, 2002, the FDA, pursuant to St. Jude Medical's application number P950022/S014, approved the Riata Series 1500 Defibrillation Lead System. (FDA PMA Database). This approval applied to Riata Model Numbers 1570, 1571, 1580, and 1581.

19. On January 23, 2003, the FDA, pursuant to St. Jude Medical's application number P950022/S015, approved an extension of the shelf-life of the Riata Leads.

20. On March 25, 2003, St. Jude Medical added two new models to the Riata Series (Model No. 1572 and 1582), when the FDA approved application number P950022/S016.

21. On April 12, 2004, the FDA approved St. Jude Medical's application number P950022/S018, a modification to the Riata defibrillation lead family to include integrated bipolar leads (Models 1560, 1561, 1562, 1590, 1591, and 1592).

22. In May of 2005, a series of applications for manufacturing modifications were approved by the FDA. These requests involved "dimensional changes" to the Riata Leads, changes from welding to crimping connectors, changes from manual to

automated processes, as well as changes to the order of the manufacturing steps for the crimping process, and "changes to the stylet ring and header coupling". *See*, application numbers: P950022/S020; P950022/S021; P950022/S022; P950022/S019; and P950022/S023.

23. On June 3, 2005, the FDA approved the addition the Riata ST Lead Models 7000, 7001, and 7002 under application number P950022/S024.

24. In March of 2006, the FDA approved the following changes to the Riata Leads: 1) modifications to the Riata ST Models 7000, 7001, and 7002 active-fixation defibrillation leads to change the geometric profile of the inner coil and add white pigment to the medical adhesive used for shock coil backfill; 2) modifications to the Riata ST Models 7000, 7001, and 7002 leads to create an active-fixation integrated bipolar lead. These devices, as modified, are marketed under the trade names Riata ST Models 7010, 7011, and 7012 and are indicated for use with compatible pulse generators; and 3) modifications to the Riata ST Models 7000, 7001, and 7002 to create a passive fixation and a passive fixation integrated bipolar lead. These devices, as modified, will be marketed under the trade names Riata ST Models 7040, 7041, and 7042 (passive fixation) and Riata ST Models 7050, 7051, 7052 (passive fixation integrated bipolar) and are indicated for use with compatible pulse generators. These changes were all included in application numbers P950022/S027 and P950022/S028.

25. In November 2006, the FDA approved St. Jude Medical's application to change the supplier for the DR-1 Boot component of its Riata Leads. (P950022/S031).

26. In December 2006, the FDA approved St. Jude Medical's application for a helix attachment modification for the Riata 1580, 1581 and 1582 leads as well as a crimp-weld coupling modification for the Riata and Riata ST lead families. (P950022/S032).

27. In February 2007, the FDA approved St. Jude Medical's application to add an automated trimming fixture to trim excess silicone adhesive on the shock electrodes during production of the Riata ST family of leads. (P950022/S033).

28. In March 2007, the FDA approved St. Jude Medical's application for changes to their Riata Leads: 1) Modification to the crimp slug weld tab; 2) Modification to the distal header assembly; 3) Modification to the PTFE liner in the IS-1 connector leg; 4) Removal of the PTFE liners in the two DF-1 connector legs; 5) Addition of a DF-1 plug accessory to the lead package; 6) Addition of an extra-soft stylet accessory to the lead package; 7) Minor modifications to the User Manual; and 8) Modified radius specification for the spring stopper component. (P950022/S034). The FDA also approved a change in the supplier of the front seal component (P950022/S035), added an "alternative welding process." (P950022/S036), and added alternate vendor of the molded connector boot for the manufacturer of Riata ST Leads (P950022/S037).

29. In June 2007, the FDA approved St. Jude Medical's application to change the suppliers of their connector rings and inner crimp sleeve components. (P950022/S038, P950022/S039, P960013/S031, and P960013/S032).

30. In October 2007, the FDA approved St. Jude Medical's application for an alternate supplier of ETFE coated cables. (P950022/S043).

31. In December 2007, the FDA approved St. Jude Medical's application to change the "shock coil backfill manufacturing process." (P950022/S046), to extend the time between plasma treatment and application of medical adhesive. (P950022/S047), and to alternate oven settings during processing of the shock coils. (P950022/S048).

32. In May 2008, the FDA approved St. Jude Medical's application to transition the manufacturing site located at Steri-Tech, Inc., Salinas, Puerto Rico for Ethylene Oxide sterilization of the pacemakers, ICDs and leads. (P950022/S045).

33. In July 2008, the FDA approved St. Jude Medical's application to transition the manufacturing of the Riata Leads to a plant in Arecibo, Puerto Rico. (P950022/S051).

34. In June 2009, the FDA approved St. Jude Medical's application for an automated heat shrinking process. (P950022/S055).

35. In September 2009, the FDA approved St. Jude Medical's application for a change in temperature and humidity cure operation, and process modifications of the DR-1 connector pin on the Durata, Riata, Riata ST and Riata ST Optim families of leads. (P950022/S064) and (P950022/S063).

36. In January 2010, the FDA approved St. Jude Medical's application for a change in the process water system monitoring frequency and locations at Arecibo, Puerto Rico manufacturing facility. (P950022/S068)

37. In May 2011, the FDA approved St. Jude Medical's application for approval of a manufacturing site at St. Jude Medical Puerto Rico LLC in Arecibo, Puerto Rico. (P950022/S067).

D. Manufacturing Defects with Regard to Riata Leads

38. From 2005-2010 St. Jude applied for over 27 manufacturing or process changes to the Riata Leads. The FDA approved these changes in a PMA and multiple supplements. Upon information and belief, St. Jude failed to manufacture the Riata Leads consistent with these approved changes, thereby creating a defective product.

39. Upon information and belief, one of these defects includes inconsistent insulation diameters surrounding the electric conductors. On information and belief, insulation diameters are required by the PMA and federal requirements to be consistent. Failure to manufacture uniform insulation diameters leads to an increased risk of abrasion at thinner insulation sites, leading to an increased risk of device failure.

40. A natural process of abrasion occurs *in situ* with the insulation surrounding the lead wires or electrical conductors. It is foreseeable that such abrasion will occur with the insulation surrounding the lead wires after implantation. As a result, the lead wires protrude through the insulation, causing them to be in contact with materials and fluids that can prevent the proper functioning of the ICD. This protrusion is called "externalization."

41. The breach of insulation and externalization of the lead wires on the Riata Leads can cause the Leads to short, and to transmit incorrect information or noise

to the pacemaker/defibrillator thereby causing it to produce unnecessary and very painful shocks of electricity, or alternatively, to fail to communicate with the pacemaker/defibrillator at which point the life-saving therapies of the device are unavailable.

42. Further upon information and belief, St. Jude inconsistently applied a lubricious interface between the inner and outer insulation in violation of the PMA. Upon information and belief, this inconsistent application may have lead to increased friction within the lead body, promoting abrasion and/or externalization.

43. Additionally, St. Jude applied and received approval for multiple changes to the cure and sterilization processes used in the manufacture of the Riata Leads. Upon information and belief, St. Jude, failed to comply with the approved methods of curing and sterilization during the manufacture of the Leads. Upon information and belief, failure to follow the approved cure and sterilization processes resulted in reduced tensile strength of the silicone insulation.

44. Finally, St. Jude applied and received approval for numerous modifications to the welding and crimping procedures in the manufacture of the Riata Leads. Upon information and belief, the PMA and Conditions of Approval required the application of a controlled, uniform degree of force when applying the crimp. Upon information and belief, failure to crimp with a controlled, uniform, degree of force, resulted in insecure crimps over the length of the Lead.

45. Failure of the Riata leads was apparently unrelated to patient age or sex, ICD indication, the primary heart disease, left ventricular ejection fraction, or lead tip

position, suggesting that manufacturing problems are responsible for the failure of the devices.

E. Recall Of The Riata Leads

46. On December 15, 2010, St. Jude Medical published a "Dear Doctor" letter regarding its Riata Leads. In the 2010 letter, St. Jude indicated that issues with defects in the insulation have been identified in the Riata Lead Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, and 7042.

47. Specifically, St. Jude states that "the Riata and Riata ST Family of Silicone Leads have exhibited an insulation abrasion rate of 0.47% over nine years of use." Additionally, St. Jude noted that the silicone used on these leads was "vulnerable to abrasion."

48. In the 2010 Dear Doctor Letter, St. Jude indicated that Lead insulation abrasion had been associated with:

a) Oversensing (leading to inhibition of pacing or inappropriate high voltage therapy);

b) Undersensing;

c) Loss of capture;

d) Changes in pacing and/or high voltage lead impedances; and

e) Inability to deliver high voltage therapy

49. Despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall of the leads at that time. Rather, St. Jude simply noted that it was "phasing-out" all Riata Lead models by the end of 2010.

50. On November 28, 2011, St. Jude Medical published a second Dear Doctor letter relating to the same set of Riata Lead Models as the 2010 Dear Doctor letter.

51. The November 28, 2011 Letter updated the previously published failure rates for the Riata Leads, indicating that it had increased to 0.63% from its 2010 rate of 0.47%. Again, despite the dangers associated with these leads, St. Jude did not initiate a voluntary recall.

52. On December 21, 2011, the FDA reclassified St. Jude's Dear Doctor advisories to a Class I Recall.

53. A Class I Recall is the most serious level of recall and is defined as: 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.

54. Specifically, the FDA indicated that the reason for the recall was that "failures associated with lead insulation abrasion on the St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads may cause the conductors to become externalized. If this occurs, this product may cause serious adverse health causes, including death."

F. Physicians Expose the Riata Lead Defects

55. Beginning in September 2011, Dr. Robert Hauser of the Minneapolis Heart Institute Foundation (MHI), began researching the FDA's MAUDE database for reported deaths related to the St. Jude Riata Leads.

56. In a manuscript sent to the *Heart Rhythm* Journal in March 2012, Dr. Hauser detailed his research and conclusions comparing the failure rates of the St. Jude Riata Leads to the reported failure rates of a competitor's leads. Hauser, R.G., Abdelhadi, R., McGriff, D., Retel, L.K., Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads (March 4, 2012) (as yet unpublished manuscript) (on file with author).

57. In his manuscript, Dr. Hauser indicated that the reports showed that 31% of the deaths involving the Riata Leads were lead-related whereas, 8% of the deaths involving the competitor's lead were found to be lead-related. *Id.* It is important to note that adverse events are often under-reported. *Id.*

58. Additionally, Dr. Hauser noted that "Abnormal high voltage impedances were the hallmark of catastrophic Riata and Riata ST lead Failure, often resulting in failure to defibrillate." *Id.* Finally, Dr. Hauser concludes that the Riata Leads are prone to high-voltage failures that have resulted in multiple deaths. *Id.*

59. On March 8, 2012, Dr. Hauser's article entitled "Here we Go Again – Another Failure in Postmarketing Device Surveillance" was published in the New England Journal of Medicine. This article exposed the increased harm in failing to have an accurate, active post-market reporting mechanism for medical devices and advocated for greater research and review of medical device failures in order to better protect patients. Robert G. Hauser, *Here We Go Again – Another Failure in Postmarketing Device Surveillance,* 366 NEW ENG. J. MED. 873, 873-75 (2012).

60. St. Jude Medical reacted to Dr. Hauser's article in what industry analysts have described as a "rare," "unprecedented," and "confounding" manner by demanding that the New England Journal of Medicine retract Dr. Hauser's article. *See* Barry Meier and Katie Thomas, *At St. Jude, Firing Back at Critics*, N.Y. TIMES, Apr. 11, 2012, at B1; Susan Kelly and Debra Sherman, *Analysis: Heart device troubles cloud St. Jude's outlook*, Reuters.com, Apr. 13, 2012, http://www.reuters.com/article/2012/04/13/us-stjude-idUSBRE83C0ME20120413.

61. In May 2012, Dr. Hauser published additional findings regarding the Riata Lead insulation defects in the Heart Rhythm Journal. Hauser, R.G., McGriff, D., Retel, L.K., Riata *Implantable Cardioverter-Defibrillator Lead Failure: Analysis of Explanted Leads with a Unique Insulation Defect* (May 2012).

V. CLAIMS FOR RELIEF

COUNT I
STRICT LIABILITY –MANUFACTURING DEFECT

62. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

63. Upon information and belief, the Riata Leads possess a manufacturing defect because the actual manufacture of the Riata Leads differs from the specifications set forth in the PMA and the conditions for approval.

64. This manufacturing defect renders the Riata Lead unreasonably dangerous for its intended use and Plaintiff could not have anticipated the danger the defect in this product created.

65. This manufacturing defect was present in the Riata Lead when it left St. Jude's control.

66. The Riata Leads were expected to and did reach Plaintiff without substantial change or adjustment to their mechanical function upon implanting the Riata Leads.

67. As a direct and proximate result of the manufacturing defect, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses, and other damages for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT II
NEGLIGENCE IN MANUFACTURING

68. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

69. Defendants have a duty to manufacture the Riata Leads consistent with the PMA and conditions of approval. Defendants breached this duty.

70. As a direct and proximate result of St. Jude's failure to manufacture the Riata Leads consistent with the PMA and conditions of approval, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses, and other damages for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT III
NEGLIGENCE PER SE

71. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

72. Federal Regulations impose standards of care on St. Jude Medical related to the manufacture, marketing, and sale of the Riata Leads.

73. Plaintiff alleges the Federal Regulations define the standard of care, and thus, St. Jude's duties are contained in, but not limited to, the following: 21 CFR 803.10; 21 CFR 803.50; 21 CFR 803.52; 21 CFR 803.53; 21 CFR 803.56; 21 CFR 806; 21 CFR 814.1; 21 CFR 814.3; 21 CFR 814.9; 21 CFR 814.20; 21 CFR 814.37; 21 CFR 814.39; 21 CFR 814.80; 21 CFR 814.82; 21 CFR 814.84; 21 CFR 820.5; 21 CFR 820.20; 21 CFR 820.22; 21 CFR 820.25; 21 CFR 820.70.

74. Plaintiff is within the class of persons the statutes and regulations protect and Plaintiff's injuries are the type of harm these statutes and regulations are to prevent.

75. Upon information and belief the Conditions of Approval for the Riata Leads incorporate these statutes and regulations. Failure to comply with the Conditions of Approval invalidates the approval order. *See* 21 CFR 814.82(c). St. Jude failed to comply with the Conditions of Approval and Federal Regulations.

76. As a direct and proximate result of St. Jude's failure to comply with the PMA and conditions of approval for manufacturing the Riata Leads, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe

emotional distress, mental anguish, economic losses and other damages for which he is entitled to compensatory and other damages and in an amount to be proven at trial.

COUNT IV
NEGLIGENCE RES IPSA LOQUITUR

77. Plaintiff hereby incorporates by reference all preceding paragraphs as if fully set forth herein.

78. The manufacturing defects found in the Riata Leads can only occur while the devices are under the control of Defendant.

79. Plaintiff's injury was of a kind that, in the ordinary course of events, would not have happened if Defendant had manufactured the Riata Leads consistent with the PMA and Conditions for Approval.

80. Defendant was responsible for the manufacturing defect that was the direct cause of Plaintiff's injury.

81. The manufacturing defect that caused the injury was not due to the actions of Plaintiff or any third person.

82. As a direct and proximate result of Defendant's negligence, Plaintiff was injured as described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

A. Economic and non-economic damages in an amount as provided by law and to be supported by the evidence at trial;

B. For compensatory damages according to proof;

C. For declaratory judgment that Defendants are liable to Plaintiff for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs, and losses caused by Defendants' wrongdoing;

D. For disgorgement of profits;

E. For an award of attorneys' fees and costs;

F. For prejudgment interest and the costs of suit; and

G. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all claims in this action.

Dated: July 23, 2012

Respectfully submitted,

ZIMMERMAN REED, PLLP

s/Genevieve M. Zimmerman

Charles S. Zimmerman, MN #120054
Ronald S. Goldser, MN #35932
Genevieve M. Zimmerman, MN #330292
Jason P. Johnston, MN #0391206
1100 IDS Center
80 South 8th St.
Minneapolis, MN 55402
(612) 341-0400

JS 44 (Rev. 09/11)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Joseph D. Houlette

(b) County of Residence of First Listed Plaintiff Dona Ana County, NM
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Genevieve M. Zimmerman, Zimmerman Reed, PLLP, 1100 IDS Center, 80 South 8th Street, Minneapolis, MN 55402

DEFENDANTS
St. Jude Medical, Inc. and Pacesetter, Inc.

County of Residence of First Listed Defendant Ramsey County, MN
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Lew Remele, Bassford Remele, 33 South Sixth Street, Suite 3800, Minneapolis, MN 55402-3707

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff) and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Med. Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*
☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 U.S.C.§ 1332
Brief description of cause:
Manufacturing defects in the St. Jude Riata and Riata ST leads

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE Honorable Susan Richard Nelson DOCKET NUMBER 12-cv-01717 SRN/JSM

DATE 7/23/2012 SIGNATURE OF ATTORNEY OF RECORD Genevieve Zimmerman

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE