

AMENDED THIS DEC 12, 2007 PURSUANT TO
MODIFIÉ CE (CONFORMÉMENT À

RULE/LA RÈGLE 26.02 (A)

Court File No.: 05-CV-292387CP

THE ORDER OF
L'ORDONNANCE DU
DATED / FAIT LE

**ONTARIO
SUPERIOR COURT OF JUSTICE**

REGISTRAR
OFFICE OF THE SUPERIOR COURT OF JUSTICE

BETWEEN:

**ADRIEN LEFRANCOIS, SALLY ANNE GEORGIU, GEORGE GEORGIU,
CYNTHIA ANN QUENNEVILLE, ROBERT QUENNEVILLE,
SHANTI DEVI PANDEY, MADHURI SINGH,
MARGARET ADELLA FITZGEORGE, WILLIAM FITZGEORGE,
HERBERT BRUCE HERON and MADELEINE MARIE HERON**

Plaintiffs

- and -

**GUIDANT CORPORATION, GUIDANT CANADA CORPORATION,
GUIDANT SALES CORPORATION and
CARDIAC PACEMAKERS INC.**

AMENDED THIS April 10/07 PURSUANT TO
MODIFIÉ CE (CONFORMÉMENT À

RULE/LA RÈGLE 26.02 ()

Defendants

THE ORDER OF Judge Cueloty
L'ORDONNANCE DU

Proceeding under the *Class Proceedings Act, 1992*

DATED / FAIT LE April 5/07

AMENDED

REGISTRAR
OFFICE OF THE SUPERIOR COURT OF JUSTICE

FRESH AS AMENDED

CONSOLIDATED STATEMENT OF CLAIM

TO THE DEFENDANT(S)

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the *Rules of Civil Procedure*, serve it on the plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, **WITHIN TWENTY DAYS** after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

THE DEFINITIONS

1. The following definitions apply for the purposes of this statement of claim:

- (a) “**Act**” means the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, as amended;
- (b) “**Adrien**” means Adrien LeFrancois;
- (c) “**Bruce**” means Herbert Bruce Heron;
- (d) “**Class**” or “**Class Members**” means all persons who were implanted in Canada with one or more of the **Defibrillators**;
- (e) “*Courts of Justice Act*” means the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;
- (f) “**CRT-D**” means an implantable cardiac resynchronization therapy defibrillator that was designed, developed, tested, manufactured, licensed, marketed, distributed or sold by the **Defendants**;
- (g) “**Cynthia**” means Cynthia Quenneville;
- (h) “**Defendants**” means collectively, **Guidant, Guidant Pacemakers, Guidant Canada, and Guidant Sales**;
- (i) “**Defibrillators**” means the following ICD and CRT-D models:

ICD and CRT-D	Model
Ventak Prizm 2 DR	1861
Contak Renewal	H135
Contak Renewal 2	H155
Contak Renewal 3	H170, H173, and H175
Contak Renewal 3 HE	H177 and H179
Contak Renewal 4	H190 and H195
Contak Renewal 4 HE	H197 and H199
Contak Renewal 3 AVT	M150 and M155
Contak Renewal 3 AVT HE	M157 and M159
Contak Renewal 4 AVT	M170 and M175
Contak Renewal 4 AVT HE	M177 and M179
Renewal RF	H230 and H235
Renewal RF HE	H239
Ventak Prizm AVT	1900
Vitality AVT	A135 and A155

- (j) **“Family Class”** or **“Family Class Members”** means the **Class Members’** family members who are entitled to assert a claim pursuant to the *FLA*;
- (k) **“FDA”** means the U.S. Food and Drug Administration;
- (l) **“FLA”** means the *Family Law Act*, R.S.O. 1990, c. F.3, as amended and equivalent or comparable legislation in other provinces;
- (m) **“George”** means George Georgiu;
- (n) **“Guidant”** means Guidant Corporation;
- (o) **“Guidant Canada”** means Guidant Canada Corporation;
- (p) **“Guidant Pacemakers”** means Cardiac Pacemakers Inc.;
- (q) **“Guidant Sales”** means Guidant Sales Corporation;
- (r) **“Health Insurance Act”** means the *Health Insurance Act*, R.S.O. 1990, c. H.6 as amended and equivalent or comparable legislation in other provinces and territories;
- (s) **“ICD”** means an implantable cardiac defibrillator that was designed, developed, tested, manufactured, licensed, marketed, distributed or sold by the **Defendants**;
- (t) **“Madeleine”** means Madeleine Heron;
- (u) **“Madhuri”** means Madhuri Singh;
- (v) **“Margaret”** means Margaret Adella Fitzgeorge;
- (w) **“Negligence Act”** means the Negligence Act, R.S.O. 1990, c.N-1 as amended and equivalent or comparable legislation in other provinces and territories;
- (x) **“OHIP”** means the Ontario Health Insurance Plan and equivalent or comparable health insurers in other provinces and territories;
- (y) **“Robert”** means Robert Quenneville;
- (z) **“Sally”** means Sally Anne Georgiu;
- (aa) **“Shanti”** means Shanti Devi Pandey; and
- (bb) **“William”** means William Fitzgeorge.

RELIEF SOUGHT

2. Adrien, Cynthia, Sally, Shanti, Margaret, and Bruce claim on their own behalves and on behalf of the Class Members:

- (a) an order pursuant to the *Act* certifying this action as a class proceeding and appointing them as the representative plaintiffs of the Class;
- (b) a declaration that the Defendants were negligent in the development, testing, design, manufacture, licensing, assembly, distribution and sale of the Defibrillators and that they are liable for damages;
- (c) a declaration that the Defendants conspired each with the other and with persons unknown;
- (d) damages, including punitive damages and the costs of administering the plan of distribution of the recovery in this action, in the sum of \$500,000,000, or such other sum as this Honourable Court finds appropriate, or alternatively, damages assessed equal to the gross revenue, or in the further alternative, damages assessed equal to the net income received by the Defendants as a result of the sale of the Defibrillators as established by an accounting if necessary;
- ~~(e)~~ an accounting and the imposition of a constructive trust over the gross revenue, or the net income, resulting from the sale of the Defibrillators in Canada and an order requiring the Defendants to disgorge the amount determined on the accounting;
- ~~(e)~~(f) such further and other special damages as may be incurred from the date hereof until the trial of the common issues, or final disposition of this action, particulars of which will be provided to the Defendants;
- ~~(f)~~(g) an order directing a reference or giving such other directions as may be necessary to determine issues not determined at the trial of the common issues;
- ~~(g)~~(h) prejudgment and postjudgment interest compounded, or pursuant to the *Courts of Justice Act*;
- ~~(h)~~(i) costs of this action pursuant to the *Act*, or in the alternative, on a substantial indemnity basis, or in the further alternative, in an amount that provides full indemnity, plus applicable taxes; and
- ~~(i)~~(j) such further and other relief as to this Honourable Court seems just.

3. Robert, George, Madhuri, William and Madeleine claim on their own behalf and on behalf of the Family Class:

- (a) an order certifying this action as a class proceeding and appointing them as the representative plaintiffs of the Family Class;
- (b) damages pursuant to the *FLA* in the amount of \$25,000,000;
- (c) prejudgment interest and postjudgment interest compounded, or pursuant to the *Courts of Justice Act*;
- (d) costs of this action pursuant to the *Act* or, alternatively, on a substantial indemnity basis; or in the further alternative, in an amount that provides full indemnity, plus applicable taxes; and
- (e) such further and other relief as to this Honourable Court seems just.

THE NATURE OF THIS ACTION

4. This action concerns the Defendants' negligent design, testing, development, manufacture, assembly, licensing, marketing, distribution, and sale of the Defibrillators, which are surgically implanted for the purposes of monitoring and correcting dangerous heart rhythms.

5. In 2005, the Defendants disclosed that the Defibrillators contained serious and life-threatening defects and that persons implanted with the Defibrillators had died.

6. If a Defibrillator malfunctions, a Class Member may suffer serious personal injury, or even death. Class Members may be required to have the Defibrillators explanted, leading to further risk of serious personal injury, or death.

7. The Plaintiffs allege that the Defibrillators are inherently defective and that the Defendants have known about the defects in the Defibrillators for a number of years, yet they continued to market the Defibrillators, and failed to disclose the defects to the Class Members and the regulatory authorities, including the FDA and Health Canada.

THE PLAINTIFFS

8. Adrien is 37 and resides in Thunder Bay, Ontario. Adrien suffers from ventricular tachycardia.

9. On December 8, 2002 Adrien was implanted with a Ventak Prizm 2 DR, model 1861 ICD, serial number 242748, at London Health Sciences Centre in London, Ontario.

10. Cynthia is 47 and resides in the City of Windsor, Ontario. Cynthia suffers from hypertrophic cardiomyopathy. This condition causes the heart muscle to thicken resulting in cardiac rhythm disturbances which can lead to sudden death.

11. On November 16, 2001, Cynthia was implanted at University Hospital in London, Ontario with a Ventak Prizm 2 DR, model 1861 ICD, serial number 215134 to regulate her cardiac rhythm.

12. Robert resides in the City of Windsor, Ontario, and is Cynthia's husband.

13. Sally is 63 and resides in the Town of Amherstburg, Ontario. Sally suffers from congestive heart failure. On or about November 17, 2003, Sally was implanted at University Hospital in London, Ontario with a Contak Renewal, model H135 CRT-D, serial number 776409.

14. George resides in the Town of Amherstburg, Ontario, and is Sally's husband.

15. Shanti is 84 and resides in the City of Saskatoon, Saskatchewan. On or about January 14, 2004, Shanti was implanted in India with a Contak Renewal 2, model H155 CRT-D, serial number 204818. On or about February 15, 2005, Shanti had this CRT-D removed because it was defective. Shanti experienced significant complications during the explant procedure.

16. On or about February 15, 2005, Shanti was implanted at Foothills Medical Centre in Calgary, Alberta with a new defibrillator, a Contak Renewal 4, model H190 ICD, serial number 300724.

17. Madhuri is a physician residing in the City of Saskatoon, Saskatchewan. Madhuri is Shanti's daughter.

18. Margaret is 58 and resides in the City of Windsor, Ontario. Margaret suffers from an irregular heart beat and valvular insufficiency. On or about March 30,

2005, Margaret was implanted at University Hospital in London, Ontario with a Contak Renewal 4, model H195 CRT-D, serial number 304866.

19. William resides in the City of Windsor, Ontario, and is Margaret's husband.

20. Bruce is 69 and resides in the City of Windsor, Ontario. He suffers from cardiac arrhythmia. On or about September 27, 2001, Bruce was implanted at St. Michael's Hospital in Toronto with a Ventak Prizm 2 DR ICD, Model 1861, serial number 215002. Bruce had his ICD explanted on August 16, 2005 at the London Health Sciences Centre in London, Ontario.

21. Madeleine resides in the City of Windsor, Ontario, and is Bruce's wife.

22. The Defendants have recalled the ICDs and CRT-Ds that are or were implanted in the plaintiffs.

THE DEFENDANTS

23. The Guidant group of companies designs, develops, tests, manufactures, assembles, licenses, markets, distributes and sells therapeutic medical devices for use in treating cardiac and vascular disease.

24. Guidant is a corporation incorporated pursuant to the laws of the State of Indiana with its world headquarters in the City of Indianapolis. The location for its Cardiac Rhythm Management Business Unit is in St. Paul, Minnesota (including customer service). Guidant is a multi-national corporation consisting of more than 50 wholly-owned subsidiaries, including Guidant Sales, Guidant Pacemakers and Guidant Canada. Guidant has offices in twelve countries, and markets its products in more than 100 countries, including Canada.

25. Guidant Canada is a corporation incorporated pursuant to the laws of the Province of Ontario, with its head office located in the Town of Markham. Guidant Canada executes Guidant's Canadian marketing strategy, makes regulatory submissions relating to Guidant's products, deals with sales and customer service, files adverse event reports with Health Canada, and is responsible for all communications with Health Canada, the Canadian medical profession, and with the Canadian Intellectual Property Office.

26. Guidant Sales is a corporation incorporated pursuant to the laws of the State of Indiana, with its principal place of business in the City of Indianapolis. Guidant Sales conceives and executes Guidant's marketing, distribution and sales strategy, including the marketing of its products in Canada.

27. Guidant Pacemakers is a corporation incorporated pursuant to the laws of the State of Indiana, with its principal place of business in St. Paul, Minnesota. Guidant

Pacemakers researched, tested, developed and manufactured Guidant's cardiac rhythm management product lines.

28. Collectively, the Defendants designed, tested, developed, manufactured, assembled, licensed, marketed, distributed, and sold the Defibrillators that were implanted into Adrien, Cynthia, Sally, Shanti, Margaret, Bruce, and the other Class Members in Ontario, Saskatchewan and across Canada.

29. At all material times, each of the Defendants was the agent of the others and each is vicariously responsible for the acts and omissions of the others as particularized herein.

THE GUIDANT GROUP OF COMPANIES

30. Guidant organized itself in such a way that the Defendants function as an ongoing, organized and continuing business unit sharing common purposes and objectives with overall management through its Management Committee.

31. Guidant's financial statements are consolidated and include the accounts of Guidant and all of its wholly-owned subsidiaries.

32. Guidant Canada is an importer and distributor of cardiovascular devices, including the Defibrillators, and holds the medical devices establishment licence for the

Defibrillators, issued by the Health Products and Food Branch Inspectorate of Health Canada, that permits Guidant to import and sell the Defibrillators in Canada. At all material times, Guidant was under a duty to report to Health Canada with respect to any defects in its products, including the Defibrillators.

33. The President of Guidant Canada, Keith E. Brauer, is the Chief Financial Officer and Vice-President, Finance of Guidant and is a member of Guidant's Management Committee. Ronald Spaulding is the President of a division of Guidant known as EMEAC, which stands for Europe, Middle East, Africa, Canada. Mr. Spaulding is also a member of the Guidant Management Committee.

34. Guidant Pacemakers holds the Medical Device Licence for the Defibrillators issued by Health Canada's Therapeutic Products Directorate/Medical Devices Bureau.

35. At all material times, the Defendants shared the common purpose of designing, testing, developing, manufacturing, licensing, assembling, marketing, distributing, and selling the Defibrillators for profit. The Defendants also shared the common purpose of concealing the defects in the Defibrillators from the Class Members, their treating physicians, and the regulatory authorities.

36. Guidant carries on business in Canada in that it has an office located at 505 Apple Creek Blvd in Markham, Ontario, premises leased by Guidant which it shares with its subsidiary, Guidant Canada. Guidant and its subsidiaries are one and the same.

37. Guidant is liable for the acts and omissions of its subsidiaries because, among other things:

- (a) it operated itself and the other Defendants as a single entity;
- (b) it completely controlled the day-to-day operations of its subsidiaries through the Management Committee, such that the subsidiaries did not function independently;
- (c) it prepared its financial statements on a consolidated basis and reported profits from the sale of the Defibrillators;
- (d) it associated its name with the Defibrillators on all packaging, in all patient manuals, and on each patient card;
- (e) it conspired with the other Defendants to manufacture, market, sell, and distribute the defective Defibrillators;
- (f) it owns the trademark "GUIDANT" which was registered in Canada on February 12, 1997;
- (g) since January 1, 2004 it has held the licence for the patents for the Defibrillators, a licence previously held by Cardiac Pacemakers;
- (h) it, along with Guidant Canada, is a lessee of the property at 505 Apple Creek Blvd in Markham, Ontario which is the registered office address for Guidant Canada;
- (i) it has a stock option plan for Guidant stock which is available to its employees, including those of its subsidiaries;
- (j) it incorporated the subsidiaries, and Guidant Canada in particular, for the primary and improper purpose of shielding the assets of Guidant from claims by the victims of their defective products in Canada; and,
- (k) to permit Guidant to avoid vicarious liability for its Canadian subsidiary would yield a result flagrantly opposed to justice and the interests of Canadians.

THE HEART AND HEART FAILURE

38. The heart is a muscular organ composed of four chambers. The heart beats more than 100,000 times per day and pumps blood which carries oxygen to the entire body. Blood from the body enters the upper two chambers of the heart, called the atria. The atria pump blood into the two lower chambers of the heart, called the ventricles. The right ventricle pumps blood to the lungs while the left ventricle pumps blood to all of the body's organs. To keep the body healthy, the heart must deliver a sufficient amount of blood to the body.

39. The heart has an electrical system that keeps the heart beat in rhythm and helps to keep the heart walls pumping in a coordinated and simultaneous fashion. The heart's electrical system is critically important to the normal functioning of the heart.

40. As a pump, the heart is most efficient in delivering blood when the heart rate is within a certain range. Normally, the heart's natural pacemaker, the sinoatrial node, keeps the heart rate in the normal range by sending out steady electrical signals. These electrical signals move down the right atrium and split into two main transmission lines to the ventricles to make them contract uniformly.

41. In some cases, the heart's electrical system functions abnormally. Tachyarrhythmia is a condition that results when the heart pumps too quickly. Bradycardia is a condition that results when the heart pumps too slowly. Both types of

abnormal heart rhythms decrease the delivery of blood by the heart which can lead to cardiac arrest and death.

42. There are two major categories of tachyarrhythmias: ventricular tachycardia and ventricular fibrillation. Ventricular tachycardia occurs when the ventricles produce impulses that make the heart beat too quickly. When the heart pumps too fast, the ventricles do not have enough time to fill their chambers with blood before the next contraction, which decreases the amount of blood delivered to the body. Ventricular tachycardia can decrease blood delivery, causing low blood pressure and progress to a more serious condition called ventricular fibrillation.

43. When ventricular fibrillation occurs, the heart beats in an irregular rhythm, as a result of multiple, rapid and chaotic electrical signals from many different areas of the ventricles. With impulses spreading irregularly throughout the heart, the heart rate rises dramatically, and the heart's ability to pump blood collapses. As a result, blood is no longer transported to the body, which leads to cardiac arrest.

44. Bradycardia is a condition that results when the heart beats too slowly to meet the body's demands. This condition is usually caused by the failure of the sinoatrial node to function properly or by a condition known as heart block. As a result, the heartbeat slows so much that the heart no longer pumps enough blood, resulting in fainting, dizziness, shortness of breath, and eventually cardiac arrest.

45. Cardiac arrest usually occurs without warning. When cardiac arrest occurs, the lack of blood flow to the brain and other body tissues results in irreversible brain damage and other organ damage, leading to death. This will occur within minutes. The only effective treatment is to restore the normal rhythm of the heart before severe damage occurs by administering a strong electrical shock to the heart to reset the heart rhythm to normal. This treatment is called defibrillation.

46. Patients need ICDs and CRT-Ds for these conditions, among others.

THE DEFIBRILLATORS

ICDs

47. An ICD is a small electronic device that is implanted inside the chest, usually under the left pectoralis muscle, to monitor the heart for any rapid, slow or irregular rhythms. When the heart is beating normally, the ICD remains inactive. If the heart develops a life-threatening tachycardia, the ICD delivers an electrical shock to the heart to terminate the abnormal rhythm and return the heart rhythm to normal.

48. The ICD may also be programmed to operate as a pacemaker so that electrical signals are sent to pace the heart when an abnormally low heart beat is detected. This function is known as bradycardia pacing. An ICD does not prevent the occurrence of life-threatening rhythms; however it can quickly terminate them when they occur.

49. An ICD consists of one or more leads and a defibrillator unit. The leads are insulated wires. The lead is inserted through a blood vessel and attached to the inner wall of the heart, while the other end is attached to the defibrillator. The leads receive the heart's electrical signals and carry those electrical signals between the heart and the defibrillator unit to monitor natural heart rhythms and help coordinate contractions. The leads also deliver electrical shocks from the defibrillator unit to the heart when tachycardia occurs.

50. An ICD has built-in bradycardia pacing capabilities because the heart may beat too slowly after it receives a defibrillating shock. If this occurs, the ICD will pace the heart until the heart rate returns to normal.

51. The defibrillator unit is a small titanium case containing a microchip computer, a capacitor and a battery. The microchip computer runs the defibrillator and constantly monitors the natural heart rhythm. The microchip instructs the capacitor to initiate an electrical signal when it detects an incorrect heart rhythm, determines the strength of the shock if necessary and keeps a record of the heart rhythms and shocks sent by the defibrillator.

CRT-Ds

52. A CRT-D provides a combination of two types of heart therapy. The first is cardiac resynchronization therapy, sometimes referred to as biventricular pacing. In healthy hearts, electricity passes through the pumping chambers very quickly, signaling

the walls of the heart to squeeze simultaneously. In diseased hearts, the electricity passes through the pumping chambers more slowly and some of the walls of the heart are squeezing, while other walls are relaxing. This pattern of contraction reduces the efficiency of the ventricles and decreases the ability of the heart to pump blood.

53. Cardiac resynchronization therapy uses a specialized pacemaker where wires are threaded to both the right and left sides of the heart. These wires work to resynchronize the action of the right and left ventricles by pacing both ventricles simultaneously. This differs from normal pacemakers which pace only the right ventricle.

54. When a person requires both cardiac resynchronization therapy and defibrillation, a CRT-D is implanted. A CRT-D works continuously to strengthen weak hearts, and shocks the heart when required.

THE DEFIBRILLATORS ARE DEFECTIVE

THE SHORT-CIRCUIT DEFECT

55. Polyimide is a type of insulation used by the Defendants to insulate the wires in the devices. Polyimide deteriorates when exposed to bodily fluids, which seep into the devices. Bodily fluids seep into the devices because the hermetic seal leaks. The deterioration of the polyimide insulation exposes the wires in the devices to fluids which cause short-circuiting and failure. The following chart indicates the devices that have the short-circuit defect (“Short-circuit Defect”):

Defibrillator	Model(s)
Ventak Prizm 2 DR	1861
Contak Renewal	H135
Contak Renewal 2	H155

56. If short-circuiting occurs, the device ceases to function and is rendered inoperative, which prevents telemetry and delivery of additional shock therapy or pacing therapy. When the device resumes function, the device's memory is erased so that the malfunction is not detectable by the physician or the patient. The malfunction is only detectable by the physician if the defibrillator is being tested at the time of the malfunction.

57. Since the memory of the defibrillator is erased, the cardiac arrhythmias are not historically detected or recorded. This can seriously compromise care provisions and medical treatment for the patients. Further, electrodes and connection wires are placed onto the heart when implanting the defibrillator, which can cause scarring. Therefore, it is difficult to remove a defibrillator without damaging the patient's adjacent muscles, and potentially damaging the heart.

THE MAGNETIC SWITCH DEFECT

58. Some of the Defibrillators are defective in that a magnetic switch inside the device becomes stuck. If a particular device is programmed with default settings, then the magnetic switch error will inhibit the treatment of ventricular or atrial tachyarrhythmias, and battery depletion will be accelerated. If a particular device is programmed with

settings other than default settings, then the device life will be significantly reduced. The following chart indicates the devices that have the magnetic switch defect:

Defibrillator	Model(s)
Contak Renewal 3	H170, H173, H175
Contak Renewal 3 HE	H177 and H179
Contak Renewal 3 AVT	M150 and M155
Contak Renewal 3 AVT HE	M157 and M159
Contak Renewal 4	H190, H195
Contak Renewal 4 HE	H197, H199
Renewal RF	H230 and H235
Renewal RF HE	H239
Contak Renewal 4 AVT	M170 and M175
Contak Renewal 4 AVT HE	M177 and M179

THE LATCHING DEFECT

59. Some of the Defibrillators are defective in that they are subject to a random memory error, which causes functional “latching” that limits available therapy. This defect results in the suspension of detection and treatment of atrial and ventricular arrhythmias. The following chart indicates the devices that have the latching defect:

Defibrillator	Model(s)
Contak Renewal 3 AVT	M150 and M155
Contak Renewal 3 AVT HE	M157 and M159
Contak Renewal 4 AVT HE	M177 and M179
Contak Renewal 4 AVT	M170 and M175
Ventak Prizm AVT	1900
Vitality AVT	A135 and A155

THE EVENTS

60. Guidant began selling the Ventak Prizm 2 DR, Model 1861 in 2000. In or before February 2002, Guidant learned that these devices had the Short-circuit Defect . In April 2002, the Defendants determined that design and manufacturing changes ought to be

implemented to correct the Short-circuit Defect. The Defendants introduced further changes in November 2002. Despite adverse event reports and their knowledge of the Short-circuit Defect, the Defendants did not disclose the defect to medical device regulators, physicians, or patients until 2005, and even after implementing the design and manufacturing changes in 2002, allowed approximately 4,000 defibrillators they knew were defective to be sold for implantation.

61. In June 2003, the Defendants' subsidiary Endovascular Technologies, Inc. pleaded guilty to ten federal felonies in the United States of America relating to selling misbranded medical devices, and failing to report over 2,600 adverse events to the FDA. As part of the plea agreement, Guidant entered into a Corporate Integrity Agreement on June 30, 2003 with the Office of Inspector General for the Department of Health and Human Services. According to the preamble of the Agreement, Guidant entered into the Agreement to:

“promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, FDA compliance regulations and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))...”

62. In or before November 2003, the Defendants became aware that the Contak Renewal, Model H135 and Contak Renewal 2, Model H155 were prone to the same Short-circuit Defect as the Ventak Prizm 2 DR, Model 1861 devices. Between November 2003 and May 2005, the Defendants received multiple reports of short-circuits among these devices. Despite these reports and their knowledge of the Short-circuit Defect, the Defendants did not disclose the defect to medical device regulators,

physicians, or patients until 2005, and continued to allow the devices to be sold for implantation despite knowledge that they were defective.

63. This constitutes a breach of Guidant's ongoing duty of disclosure of defects under Canadian and U.S. law and a violation of its duty under the Corporate Integrity Agreement described in paragraph 61 above.

64. On May 23, 2005, the day before a *New York Times* article was scheduled to be published regarding a death that had been linked to a defective Guidant heart device, the Defendants acknowledged the existence of the defect in the Ventak Prizm 2 DR, Model 1861. This was done through a "Dear Doctor" letter to U.S. physicians who were known to the Defendants to have implanted or to have been monitoring patients implanted with the device. This was the first time Guidant had made any public disclosure of the defect.

65. On June 17, 2005, the Defendants issued a Dear Doctor letter advising that it would be recalling the Ventak Prizm 2 DR, Model 1861. In the letter, Guidant disclosed that it had made manufacturing changes to prevent the Short-circuit Defect on April 16, 2002 and on November 13, 2002.

66. On June 17, 2005, the Defendants publicly acknowledged that the Contak Renewal, Model H135 and the Contak Renewal 2, Model H155 CRT-Ds are also subject to the Short-circuit Defect. On June 20 2005, Health Canada conveyed this information to Canadian health care professionals.

67. On June 17, 2005, the Defendants publicly acknowledged that the Ventak Prizm AVT, Model 1900, Vitality AVT, Models A135 and A155, and Contak Renewal 3 AVT, Models M150 and M155, Contak Renewal 3 AVT HE, Models M157 and M159, Contak Renewal 4 AVT, Models M170 and M175, and Contak Renewal 4 AVT HE, Models M177 and M179 ICDs are subject to the latching defect. On June 20, 2005, Health Canada conveyed this information to Canadian health care professionals.

68. On June 23, 2005, the Defendants publicly acknowledged that the Contak Renewal 3, Models H170, H173, and H175, Contak Renewal 3 HE, Models H177 and H179, Contak Renewal 3 AVT, Models M150 and M155, Contak Renewal 3 AVT HE, Models M157 and M159, Contak Renewal 4, Models H190 and H195, Contak Renewal 4 HE, Models H197 and H199, Renewal RF, Models H230 and H235, Renewal RF HE, Model H239, Contak Renewal 4 AVT, Models M170 and M175, and Contak Renewal 4 AVT HE, Models M177 and M179 ICDs are subject to the magnetic switch defect. On June 24 2005, Health Canada conveyed this information to Canadian health care professionals.

69. The FDA classified the Defendants' actions regarding the Ventak Prizm 2 DR, Model 1861, the Contak Renewal, Model H135, the Contak Renewal 2, Model H155, Ventak Prizm AVT, Model 1900, the Vitality AVT, Models A135 and A155, the Contak Renewal 3 AVT, Models M150 and M155, the Contak Renewal 3 AVT HE, Models M157 and M159, the Contak Renewal 4 AVT, Models M170 and M175, and the Contak Renewal 4 AVT HE, Models M177 and M179 as Class I recalls. A Class I recall is one in

which there is a reasonable probability that if a particular device malfunctions it will cause serious adverse health consequences or death.

70. The FDA classified the Defendants' actions regarding the remaining devices as Class II recalls. A Class II recall is one in which the malfunctioning product may cause temporary or medically reversible adverse health consequences.

71. In June, 2005 the Defendants commissioned an independent panel of experts to assess and evaluate their operations. On March 20, 2006, the panel released its report. The report brought to light a number of the Defendants' failings, including their:

- (a) failure to enforce its policy on patient safety;
- (b) systemic lack of quality assurance systems;
- (c) policy of permitting performance within anticipated adverse event rates to pre-empt patient safety in the evaluation of device performance;
- (d) failure to discharge its obligation to warn physicians and patients;
- (e) ineffective post-market surveillance process;
- (f) lack of an independent committee of experts to evaluate product performance and risk assessment data; and
- (g) lack of an independent committee of experts to advise on actions to be taken regarding device failures and malfunctions.

THE CONSPIRACY

72. From on or about January 1, 1994 to on or about June 24, 2005, at Indianapolis, Indiana, St. Paul, Minnesota, Markham, Ontario and elsewhere, the Defendants by their directors, officers, servants and agents, wrongfully, unlawfully,

maliciously, and lacking *bona fides*, conspired and agreed together, the one with the other and with persons unknown to:

- (a) submit false, inaccurate, incomplete, and misleading information to Health Canada and the FDA;
- (b) conceal the defects in the Defibrillators;
- (c) mislead the Class Members and others about the safety of Defibrillators; and
- (d) delay the repairs of the defects in the Defibrillators.

73. The Defendants were motivated to conspire and their predominant purposes, concerns, and motivations were:

- (a) to obtain medical device licences and other approvals for Defibrillators;
- (b) to increase or maintain revenue;
- (c) to increase or maintain profit;
- (d) to increase or maintain market share;
- (e) to avoid negative publicity;
- (f) to place corporate revenue and profit above the safety of the Class Members; and
- (g) to avoid the costs associated with correcting the defects in the Defibrillators.

74. In furtherance of the conspiracy, the following acts, among others, were done by the Defendants and their servants, agents, and employees:

- (a) they met secretly in the United States and Canada from time to time to discuss the issues giving rise to the conspiracy;
- (b) they directed their servants, agents, and employees to perform wrongful or unlawful acts in furtherance of the conspiracy;

- (c) they failed to disclose the defects in the Defibrillators to the public and the regulatory authorities in a timely manner or at all;
- (d) they failed to take any steps to cure the defects in Defibrillators after they knew of the defects and the injuries and risks associated with the use of the devices;
- (e) they failed to warn the Class Members, health care providers, the medical community, and others that the Defibrillators were defective;
- (f) they concealed the fact that the Defibrillators were defective from the Class Members, health care providers, the medical community, and regulatory authorities, including Health Canada and the FDA;
- (g) they concealed information regarding the testing and safety of the Defibrillators from the Class Members, health care providers, the medical community, and regulatory authorities, including Health Canada and the FDA;
- (h) they continued to sell the Defibrillators after knowledge of the defects in order to exhaust the existing inventories;
- (i) they suppressed the recommendations of the Independent Panel of Experts, and concealed their non-compliance with the Panel's recommendations;
- (j) they gave inadequate information to physicians and failed to ensure that accurate and reliable information was conveyed to patients in a timely manner or at all; and,
- (k) they failed to ensure that patients were given accurate information regarding the nature of the defect and options to rectify the problem in a timely manner or at all.

75. The Defendants' conduct was unlawful because they knowingly marketed and sold the Defibrillators and permitted them to be implanted into the Class Members. Despite knowing that the Defibrillators were defective, the Defendants concealed the defects from the Class Members, health care providers, the medical community, and regulatory authorities, including Health Canada and the FDA contrary to their common law obligations and their statutory and regulatory obligations contained in s. 19 to 21 of the *Foods and Drug Act*, R.S. 1985, c. F-27 and sections 10 to 13, 59 to 61.1 and 64 to

65.1 of the *Medical Devices Regulations*, SOR/98-282 and U.S. legislation and regulations, including the *Federal Food, Drug and Cosmetic Act*, United States Code, Title 21, Chapter 9 and related regulations.

76. The conspiracy was directed towards the Plaintiffs and the other Class Members. The Defendants knew that the Class Members would be implanted with the Defibrillators. The Defendants knew that the conspiracy would cause injury to the Plaintiffs, the Class Members and other Family Class members, and it did.

THE DEFENDANTS' NEGLIGENCE

77. The Defendants owed a duty of care to the Class Members and breached the standard of care expected in the circumstances.

78. The Defendants were negligent in the research, design, development, pre-market testing, manufacturing, licensing, assembly, distribution, marketing, sale, post-market testing and post-market surveillance of the Defibrillators. Particulars of the acts of negligence include:

- (a) they knew that the Defibrillators were dangerously defective and failed to warn the patients, health care providers and the regulatory authorities;
- (b) they failed to disclose the defects in the Defibrillators to the public and the regulatory authorities in a timely manner;
- (c) they continued to sell the Defibrillators with design defects after the design change in 2002;
- (d) they failed to collect and analyze information about the performance of the Defibrillators;

- (e) they improperly collected and analyzed information about the performance of the Defibrillators;
- (f) they collected and analyzed information about the performance of the Defibrillators but failed to conclude that a field action was necessary;
- (g) they collected and analyzed information about the performance of the Defibrillators, concluded that a field action was necessary but failed to perform a field action;
- (h) they failed to adequately design, manufacture and test the Defibrillators to ensure that they were safe and free from defects prior to selling or distributing them;
- (i) they failed to properly train their employees responsible for the design, testing, assembly and manufacture of the Defibrillators;
- (j) they failed to ensure that their employees complied with the appropriate quality system standards applicable to the manufacturing process;
- (k) they failed to properly supervise their employees and subsidiaries;
- (l) they distributed and sold the Defibrillators without conducting tests to ensure they were defect-free;
- (m) they performed inadequate tests and clinical studies to determine whether the Defibrillators were defective or would be susceptible to defects over time;
- (n) they failed to conduct testing in accordance with good laboratory practice and relevant International Organization for Standardization standards;
- (o) they failed to properly record the results of testing the Defibrillators;
- (p) they failed to interpret or report the data from pre-market testing in an accurate and objective manner;
- (q) they failed to adequately test the Defibrillators particularly in light of previous failures in other devices;
- (r) they failed to properly report the results of testing the Defibrillators;
- (s) they knew or ought to have known that the Defibrillators were defective and that they would not properly perform the functions for which they were intended;
- (t) they failed to ensure that the component and device characteristics were fully monitored and controlled during production;

- (u) they failed to take any steps to cure the defects in the Defibrillators after they knew of the defects and the injuries and risks associated with their use;
- (v) they failed to perform, adequately or at all, trend analysis to monitor the post-market performance of the Defibrillators;
- (w) they failed to report, adequately or at all, in a fair, objective and unbiased manner, the results of post-market adverse event investigations;
- (x) they failed to warn the Class Members that the Defibrillators were defective when knowledge of the defects became known to them;
- (y) they failed to warn health care providers that the Defibrillators were defective when knowledge of the defects became known to them;
- (z) they preferred their commercial interests over patient safety;
- (aa) they failed to ensure that wire insulators within the connector block of the Defibrillators would not deteriorate and cause a short-circuit;
- (bb) they used polyimide to coat electrical wires inside the Defibrillators when they knew or should have known that the polyimide would deteriorate and cause short-circuits;
- (cc) they failed to design the header in the Defibrillators in such a way as to ensure it was hermetically sealed;
- (dd) they used polyimide inside the Defibrillator header when they knew or should have known that it was unsafe to do;
- (ee) they used polyimide when the industry standard was to only use polyimide if the material was permanently shielded from moisture;
- (ff) they failed to ensure that the Defibrillators' hermetic seal would not leak;
- (gg) they failed to ensure that the Defibrillators' internal memory would not fail;
- (hh) they failed to ensure that the magnetic switches inside the Defibrillators would not stick;
- (ii) they used defective components to manufacture the Defibrillators;
- (jj) they failed to ensure that the Defibrillators' history records included complete acceptance records that demonstrated that the devices were manufactured in accordance with the device master record;

- (kk) they failed to ensure that during the production of the Defibrillators, component and device characteristics were fully monitored and controlled;
- (ll) they knew or should have known that the design, materials and manufacture of the Defibrillators would unreasonably increase the risks of device failure;
- (mm) they failed to enforce policies regarding patient safety;
- (nn) they operated without any system of quality assurance;
- (oo) they failed to ensure that appropriate sources of quality data were adequately analyzed to identify existing and potential causes of nonconforming product and other quality problems;
- (pp) they permitted performance within anticipated adverse event rates to preempt patient safety in the evaluation of device performance;
- (qq) they failed to constitute an independent committee of experts to evaluate product performance and risk assessment prior to June, 2005;
- (rr) they failed to constitute an independent committee of experts to advise on actions to be taken regarding device failures and malfunctions;
- (ss) they knew or should have known that the Defibrillators were susceptible to unreasonable failure rates;
- (tt) they failed to ensure that procedures for conducting quality audits were complete;
- (uu) they failed to establish an effective post-market surveillance process;
- (vv) they failed to abide by the terms of the Corporate Integrity Agreement entered into on June 30, 2003;
- (ww) they concealed the fact that the Defibrillators were defective from the public, health care providers and the regulatory authorities, including the FDA and Health Canada;
- (xx) they continued to sell the Defibrillators notwithstanding receipt of negative data from post-market testing and adverse event reports from the clinical use of the Defibrillators;
- (yy) they delayed reporting adverse events to the FDA and Health Canada in an attempt to forestall regulatory scrutiny of the safety and efficacy of the Defibrillators;

- (zz) they failed to investigate, adequately or at all, adverse event reports; and
- (aaa) they concealed adverse information regarding the testing and safety of the Defibrillators from the public, health care providers and regulatory authorities, including the FDA and Health Canada.

DAMAGES

79. Adrien, Cynthia, Sally, Shanti, Margaret, and Bruce plead that they and the other Class Members would not have had the Defibrillators implanted, and thereby suffered damages, had the Defendants not conspired and acted negligently and had they disclosed the defects that were known to them in a timely manner.

80. As a result of the Defendants' negligence, the conspiracy and their conduct described above, Adrien, Cynthia, Sally, Shanti, Margaret, Bruce, and the other Class Members have suffered damages and losses, including, but not limited to:

- (a) enduring or having to endure painful medical procedures to implant the Defibrillators;
- (b) enduring or having to endure painful medical procedures to explant the Defibrillators;
- (c) enduring painful medical procedures to implant new defibrillators that are defect-free;
- (d) personal injury, including adverse effects of the diseases which necessitated the implant of the Defibrillators in the first place;
- (e) emotional distress, including mental distress, anger, depression and anxiety;
- (f) the risk of death or other serious injuries;
- (g) costs associated with replacing the Defibrillators;
- (h) costs associated with monitoring the Defibrillators;

- (i) out-of-pocket expenses incurred by the Class Members or for their benefit; and
- (j) loss of income.

81. As a result of the Defendants' negligence, the conspiracy and their conduct described above, Robert, George, Madhuri, William, Madeleine, and the other Family Class Members have suffered damages, including, but not limited to:

- (a) actual expenses reasonably incurred for the benefit of the Class Members;
- (b) traveling expenses incurred while visiting the Class Members during treatment or recovery;
- (c) loss of income or the value of services provided for the Class Member where services, including nursing and housekeeping, have been provided; and
- (d) compensation for loss of support, guidance, care and companionship that they might reasonably have expected to receive from the Class Member.

PUNITIVE DAMAGES

82. The Plaintiffs plead that the Defendants' conduct in the design, development, testing, manufacture, licensing, assembly, distribution, marketing, and sale of the Defibrillators, the delayed recall and/or the failure to recall the Defibrillators, and the facts pleaded above, was high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, disgraceful, willful, and in intentional disregard of the Class Members' rights and safety, indifferent to the consequences, and motivated by economic considerations such as maintaining revenue and market share. Such conduct renders the Defendants liable to pay punitive damages.

WAIVER OF TORT

83. As a result of the Defendants' conduct described ~~herein~~ in paragraphs 4 to 7 and 23 to 79, the Plaintiffs reserve to themselves the right to elect at the trial of the common issues to waive the torts of negligence and/or conspiracy and to have damages assessed in an amount equal to the gross revenue received by the Defendants, or alternatively, the net income received by the Defendants as a result of the sale of the Defibrillators as pleaded in paragraph 2(d) above.

83A. The Defendants hold the gross revenue or, alternatively, the net revenue from the sale of the Defibrillators in Canada as constructive trustees for the Class Members and should be required to disgorge the amount found due as a result of an accounting because:

- (a) the relationship between the Defendants, who were the designer, manufacturer and distributor of implantable medical devices and the vulnerable Class Members, into whom the Defibrillators were implanted, was based on the Class Members trusting the Defendants and relying upon them to act with the utmost integrity;
- (b) the Defendants cannot benefit from their conspiracy and negligence which was wrongful conduct; and
- (c) good conscience requires the Defendants to hold in trust the revenue they received from the sale of the Defibrillators in Canada and to disgorge this revenue to the Class Members.

PROVINCIAL HEALTH INSURERS

84. OHIP has incurred various expenses with respect to the purchase of the defibrillators, and the medical treatment of the plaintiffs and Class Members as a result of the Defendants' negligence. As a result, OHIP has suffered and will continue to suffer damages for which it is entitled to be compensated by virtue of its subrogated and direct rights of action in respect of all past and future insured services. This action is maintained on behalf of all provincial and territorial health insurers.

LEGISLATION

85. The Plaintiffs plead and rely upon, *inter alia*:

- *Alberta Health Care Insurance Act*, R.S.A. 2000, c. A-20
- *Class Proceedings Act, 1992*, S.O. 1992, c. 6;
- *Courts of Justice Act*, R.S.O. 1990, c. C.43;
- *Department of Health Act*, R.S.S. 1978, c. D-17;
- *Federal Food, Drug and Cosmetic Act*, United States Code, Title 21, Chapter 9;
- *Food and Drugs Act*, R.S. 1985, c. F-27 and applicable regulations, including the *Medical Device Regulations*, SOR/98-282;
- *Family Law Act*, R.S.O. 1990, c. F.3;

- *Fatal Accident Act*, R.S.N.L. 1990, c. F-6;
- *Fatal Accidents Act*, C.C.S.M. c. F50;
- *Fatal Accidents Act*, R.S.A. 2000, c. F-8;
- *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7;
- *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3;
- *Fatal Accidents Act*, R.S.P.E.I. 1988 c. F-5;
- *Fatal Accidents Act*, R.S.S. 1978, c. F-11;
- *Fatal Accidents Act*, R.S.Y. 2002, c. 86;
- *Fatal Injuries Act*, R.S.N.S. 1989, c. 163;
- *Health Insurance Act*, R.S.O. 1990, c. H.6;
- *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197;
- *Health Services Insurance Act*, C.C.S.M., c. H35;
- *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988 c. H-8;
- *Hospital Insurance Agreement Act*, R.S.N.L. 1990 c. H-7;
- *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3;

- *Hospital Insurance Services Act*, R.S.Y. 2002, c.112;
- *Hospital Services Act*, R.S.N.B. 1973, c. H-9;
- *Hospitals Act*, R.S.A. 2000, c. H-12;
- *Negligence Act*, R.S.O. 1990, c. N.1;
- *Trustee Act*, C.C.S.M. c. T160;
- *Trustee Act*, R.S.N.W.T. 1988, c. T-8; and
- *Trustee Act*, R.S.O. 1990, c. T.23.

REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO

86. The plaintiffs plead that this action has a real and substantial connection with Ontario because, among other things:

- (a) the Defendants carry on business in Markham, Ontario;
- (b) the Defendants distribute and sell their products in Ontario and derive substantial revenue from such sales;
- (c) Adrien, Cynthia, Sally, Margaret, and Bruce's damages, and those of the other Class Members resident in Ontario, were sustained in Ontario;
- (d) Robert, George, William, and Madeleine's damages, and those of the other Family Class Members resident in Ontario, were sustained in Ontario;
- (e) the Defendants made application to Health Canada in Ottawa, Ontario for permission to market the Defibrillators in Canada;
- (f) the Defendants advertised their products, including the Defibrillators in Ontario;

- (g) the Defendants registered the trademark “GUIDANT” with the Canadian Intellectual Property Office in Ottawa; and
- (h) the Defendants hold the licence to the patents for the Defibrillators which patents are registered with the Canadian Intellectual Property Office in Ottawa.

SERVICE OUTSIDE OF ONTARIO

87. This originating process may be served without court order outside Ontario because the claim is:

- (a) in respect of a tort committed in Ontario (rule 17.02(g));
- (b) in respect of damages sustained in Ontario arising from a tort or breach of contract however committed (rule 17.02(h));
- (c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and,
- (d) against a person carrying on business in Ontario (rule 17.02(p)).

THE PLACE OF TRIAL

88. The Plaintiffs propose that this action be tried at the City of Toronto, in the Province of Ontario.

Date: June 29, 2005

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PLAINTIFFS

- and -

GUIDANT CORPORATION, et al
DEFENDANTS

Court File No. 05-CV-292387CP

**ONTARIO
SUPERIOR COURT OF JUSTICE**

Proceeding commenced at Toronto
Proceeding under the *Class Proceedings Act*, 1992

**AMENDED
FRESH AS AMENDED CONSOLIDATED
STATEMENT OF CLAIM**

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