05-CV-295630CP

COURT FILE NO.

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

HERBERT BRUCE HERON

PLAINTIFF

- AND -

GUIDANT CORPORATION, GUIDANT SALES CORPORATION, GUIDANT CANADA CORPORATION, AND CARDIAC PACEMAKERS, INC.

DEFENDANTS

PROCEEDING UNDER THE *CLASS PROCEEDINGS ACT*, 1992

STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. 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 plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, 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.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

If you wish to defend this proceeding but are unable to pay legal fees, legal aid may be available to you by contacting the Legal Aid Office.

DATE: August 22 2005 **ISSUED BY:** M. Brenton

REGISTRAR (M. Brenton)

ADDRESS OF COURT OFFICE:
393 University ~~Avenue~~
~~Toronto~~, ON M5G 1E8

TO: GUIDANT CORPORATION
111 Monument Circle, #2900
Indianapolis, IN
United States of America
46204-5129

SUPERIOR COURT
OF JUSTICE
393 UNIVERSITY AVE.
10TH FLOOR
TORONTO, ONTARIO
M5G 1E6

COUR SUPÉRIEURE
DE JUSTICE
393 AVE. UNIVERSITY
10E ÉTAGE
TORONTO, ONTARIO
M5G 1E6

AND
TO: GUIDANT SALES CORPORATION
111 Monument Circle, #2900
Indianapolis, IN
United States of America
46204-5129

AND
TO: GUIDANT CANADA CORPORATION
505 Apple Creek Blvd., Unit 4
Markham, Ontario
Canada
L5R 5B1

AND
TO: CARDIAC PACEMAKERS, INC.
4100 Hamline Avenue North
St. Paul, Minnesota
United States of America
55112-5798

CLAIM

1. The plaintiff claims, on his own behalf and on behalf of all class members:

   (a) an order certifying this action as a class proceeding, appointing him as the representative plaintiff and appointing his counsel as class counsel;

   (b) a declaration that the defendants owed a duty of care to the plaintiff and the class members, and that the defendants negligently breached that duty in respect of their research, development, pre-market testing, manufacturing, representation to regulators, post-market surveillance, warning and recall of their defective defibrillators and pacemakers (as listed in paragraphs 17 and 18, below), and that the defendants are liable to the class for damages;

   (c) an order requiring the defendants to fund the cost of medical monitoring of all patients implanted with defective Guidant defibrillators and pacemakers;

   (d) general damages in the amount of $250 million dollars;

   (e) special damages in the amount of $250 million dollars, or such other amount as this Honourable Court may find appropriate;

   (f) punitive, aggravated and exemplary damages in the amount of $10 million dollars, or such other amount as this Honourable Court may find appropriate;

   (g) refunds to all purchasers of the defective Guidant defibrillators and pacemakers;

(h) a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

(i) pre-judgment interest pursuant to the Courts of Justice Act, R.S.O. 1990, c. C43, as amended;

(j) costs of this action on a substantial indemnity scale, plus G.S.T.; and

(k) such further and other relief as to this Honourable Court may seem just.

THE PARTIES

2. The plaintiff, Herbert Bruce Heron ("Bruce"), resides in the City of Windsor, Ontario. On September 27, 2001, Bruce was implanted with a Ventak Prizm 2 DR Automatic Implantable Cardioverter Defibrillator ("AICD") Model 1861, serial number 215002, manufactured by Guidant Corporation. Bruce needed an implantable defibrillator to protect him from cardiac arrest because of his history of severe cardiac arrhythmia.

3. Bruce's device was one of several models of Guidant devices affected by the Food and Drug Administration ("FDA") Class I recall of July 1, 2005.

4. As part of the recall notification, Bruce learned that his AICD had a defect that could cause it to malfunction. He also discovered that, at this time, there was no way of knowing when the device would fail. What was known

was that, if the device did fail, it would likely result in death or serious injury. Bruce, in consultation with his treating physicians, decided to have his device explanted when he learned of the risk of failure of his device, the probability of death or irreversible injury in the event of device failure, and the inability of the defendants to predict which devices will fail and when they will fail.

5. Bruce had his AICD explanted on August 16, 2005.

6. As a result of learning through the recall process that the defendants knew that his device was defective, but had not told him until 3 years later, and only upon being forced to do so, Bruce has lost confidence that the defendants will in the future act as a responsible device manufacturer should.

THE DEFENDANTS

7. The defendant, Guidant Corporation, is an American corporation, with its world-wide headquarters in Indianapolis, Indiana, U.S.A. (hereinafter all defendants are described as "Guidant" unless otherwise stated). Guidant is a cardiac medical device company which derives almost 50% of its total annual earnings from its cardiac rhythm management line of products, which includes 3 families of devices: AICD's, cardiac resynchronization therapy defibrillators ("CRT-D's"), and pacemakers.

8. The defendant, Guidant Sales Corporation ("Guidant Sales"), is a wholly owned subsidiary of Guidant, operating from its world-wide headquarters in Indianapolis, Indiana, U.S.A. This wholly owned subsidiary conceives and executes Guidant's marketing, distribution and sales strategy world-wide, including the marketing of its cardiac rhythm management products in Canada.

9. The defendant Guidant Canada Corporation ("Guidant Canada") is located in Markham, Ontario, and is a wholly owned subsidiary of Guidant. From these Canadian offices it executes Guidant's Canadian marketing strategy, makes regulatory submissions related to its cardiac rhythm management product lines, makes adverse event reports to the regulator, Health Canada, in Ottawa, and is responsible for all communications with the regulator, the medical profession and Canadian device patients.

10. The defendant, Cardiac Pacemakers, Inc. ("Cardiac Pacemakers") is a wholly owned subsidiary of Guidant, located at Guidant's Cardiac Rhythm Management offices in St. Paul, Minnesota, U.S.A. Cardiac Pacemakers is a wholly-owned subsidiary through which Guidant researched, tested, developed and manufactured its various cardiac rhythm management product lines.

11. Guidant wholly owns Guidant Sales, Guidant Canada and Cardiac Pacemakers, and exercises actual and effective control over these corporations with the common purpose of developing, testing, manufacturing, distributing, marketing and sales, communicating with its regulators pre and post market, and monitoring and reporting adverse events in Canada. The plaintiff pleads that Guidant is vicariously liable for the acts and omissions of Guidant Canada, Guidant Sales and Cardiac Pacemakers because it controlled all the day to day operations of its subsidiaries, had common officers and directors, and operated as a single business entity in Canada.

THE CLASSES

12. This action is brought on behalf of the following classes of persons:

Class 1 Members:

"All persons in Canada, other than those resident in British Columbia and Quebec, who have been implanted with Guidant AICD's, CRT-D's, and pacemakers (as set out in paragraphs 17 and 18 of the Statement of Claim), researched, designed, tested, developed, manufactured, distributed, marketed and sold by the defendants."

Class 2 Members:

"All persons, including executors, administrators, personal representatives,

spouses and relatives who, by reason of a personal relationship to a Class 1 member, have a derivative claim for damages.

GUIDANT'S DEFECTIVE DEVICES

Cardiac Rhythm Management Generally

13. The heart is the organ which pumps blood through the circulatory system, taking oxygenated blood throughout the body and returning de-oxygenated blood to the lungs to be replenished. In order to operate effectively, the two upper chambers (atria) and the two lower chambers (ventricles) of the heart must contract in a harmonious, synchronized manner, within a certain range of beats per minute. Channels running through the walls of the four chambers deliver synchronized electrical stimulation to each of the heart's chambers, which keeps the heart beating in a synchronized rhythmic mode. Where a patient suffers from cardiac disease or electrophysiological dysfunction, the heart's ability to pump may become impaired, resulting in poor blood circulation. Damage to the electrical channels through the heart can lead to too rapid a heart beat (tachycardia), too slow a heart beat (bradycardia), or a chaotic unsynchronized heart beat (fibrillation).

14. Over the last decade, Guidant and other cardiac rhythm management device companies developed new devices to address the needs of cardiac patients with arrhythmias. During that time, Guidant has aggressively marketed its

cardiac rhythm management product lines as being safe and effective, durable, and free from defects, as well as having admirably low failure rates.

15. All Guidant cardiac rhythm management devices operate through a pulse generator, which is implanted below the skin in an area in the upper left chest, above the heart and below the shoulder. One or more electrical leads are implanted into the walls of one or more chambers of the heart, and are attached to the pulse generator. Software within the pulse generator is programmed to deliver individualized therapy to the patient, depending on his or her particular electrophysiological needs. Sensors in the leads relay information back to the device, based on which the device will deliver the programmed therapy adjusted to need. A battery is contained within the pulse generator, from which electrical therapy is delivered as the soft-ware commands. The devices and the leads are insulated against the implant environment so as to safeguard the electrical integrity of the device.

16. When functioning properly, an AICD, CRT-D or pacemaker can save lives. However, if the device fails to provide therapy during an arrhythmic episode or otherwise, a patient can go into cardiac arrest, and has only minutes before permanent injury or death occurs, if medical intervention is not available.

17. Through its subsidiaries and affiliated companies, Guidant designed, manufactured, and distributed the following models of AICD's and CRT-D's, which were defective:

a. Ventak Prizm 2 VR, Model 1860;

b. Ventak Prizm 2 DR, Model 1861;

c. Ventak Prizm VR, Models 1850/1855;

d. Ventak Prizm DR, Models 1851/1856

e. Ventak Prizm VR HE, Models 1852;

f. Ventak Prizm DR HE, Models 1852;

g. Ventak Prizm DR HE, Models 1853;

h. Ventak Mini IV, Models 1790/1793/1796;

i. Ventak Mini III HE, Model 1789;

j. Ventak Prizm AVT (all series numbers);

k. Vitality AVT (all series numbers);

l. Contak Renewal 2, Model H155;

m. Contak Renewal 3;

n. Contak Renewal 4;

o. Contak Renewal 3 AVT (all series numbers);

p. Contak Renewal 4 AVT (all series numbers);

q. Contak Renewal RF

18. Through its subsidiaries and affiliated companies, Guidant also designed, manufactured and distributed the following pacemakers, which were defective:

    a. PULSAR® MAX

    b. PULSAR

    c. DISCOVERY®

    d. MERIDIAN®

    e. PULSAR MAX II

    f. DISCOVERY II

    g. VIRTUS PLUS® II

    h. INTELIS II

    i. CONTAK® TR

19. All of the aforementioned devices are prone to failure, and have either been withdrawn from the market by the defendant, subject to world-wide safety notifications by the defendant, or subject to FDA Class 1 or Class 2 recalls.

HISTORY OF DEVICE FAILURES AND RECALLS

20. The Ventak Prizm AICD was originally approved for sale in the U.S.A. on June 17, 1994, and in Canada thereafter. On July 18, 2002, under a supplemental approval, the FDA agreed to expand the approved indications for all Ventak Prizm AICD's, to the prophylactic treatment of patients with

prior heart attacks and an ejection fraction of 30% or more. This supplemental approval allowed the defendants to market its AICD's to a far broader range of patients, thereby increasing the size of the market considerably.

21. From 1998 to 2001, over 13,000 of the defendants' Ventak Prizm AICD's were subject to recalls, for model numbers 1850, 1851, 1852, 1853, 1857 and 1858 (the "1850's series" of models). The reason for the recalls of these models was that the insulation degenerated, leading to exposure of electrical elements, and resulting in short-circuits and loss of function for 24 hour cycles.

22. In the time period 2000 to 2002, the defendants introduced AICD model numbers in the 1860's series, to replace the AICD models in the 1850's series, which had been withdrawn from the market or recalled. In that same time period, the defendants became aware that the AICD's in the 1860's model range were experiencing the same problems as had been encountered in the 1850's models - that is, insulation failure leading to short circuiting, loss of function for 24 hour periods, and erasure of the device's memory. When the device's memory is erased, arrhythmic episodes are not detected or recorded, making treatment recommendations seriously problematic.

23. In mid to late 2002, the defendants attempted to rectify the defect by introducing manufacturing changes to the AICD's. These changes were initiated without adequate research and testing to ensure that these modifications would make the device safe and effective over the middle to later life of the device.

24. While recognizing that its AICD's were defective and implementing design and manufacturing changes, the defendants continued to sell the defective models, failed to notify patients with the defective AICD's implanted, and failed to notify treating physicians and regulators about this defect.

25. The defendants' failure to warn patients, their treating physicians, and regulators continued for three years, until May, 2005, when media reports investigating the death of a young patient who was implanted with a Ventak Prizm 2 DR Model 1861 on October 4, 2001, forced Guidant to break its silence. After investigation by the treating physicians of the deceased, it was learned that his device had malfunctioned due to the same defect for which the defendants had introduced the design and manufacturing changes in 2002. The device short-circuited due to insulation degradation, the AICD failed to deliver the high voltage defibrillator shock following cardiac arrest, and the young patient died on March 14, 2005, more than 3 years after Guidant knew about the existence of this type of defect.

26. On May 23, 2005, Guidant advised physicians of a failure in its Ventak Prizm 2 DR Model 1861 AICD. In its "Dear Doctor" letter, Guidant disclosed that it was aware of 26 reports of failure including a recent death involving the Ventak Prizm 2 DR AICD's manufactured prior to November, 2002.

27. On June 17, 2005, Guidant made a world-wide safety notification regarding the AICD's and CRT-D's, more than 80,000 of which had been implanted in patients. Approximately, 42,000 of the Ventak Prizm 2 DR and Contak Renewal 2 devices are affected by the notification (approximately 20,000 of which are still implanted). In addition, approximately 46,000 of the Contak Renewal 3 and 4, Renewal 3 and 4 AVT and Renewal RF devices are affected by the notification.

28. On June 24, 2005, Guidant made a world-wide safety notification to physicians regarding the Contak Renewal 3 and 4, Renewal 3 and 4 AVT and Renewal RF families of devices. The common device defect related to a magnetic switch failure which impaired these devices' ability to deliver therapy, which can lead to accelerated battery depletion.

29. On July 1, 2005, the FDA classified Guidant's various notifications as either Class 1 or Class 2 recalls. A Class 1 recall indicates that there is a reasonable probability that if the particular device malfunctions, it will cause irreversible adverse health consequences or death. A Class 2 recall

indicates that a device malfunction can cause temporary or medically reversible adverse health consequences.

30. The families of devices designated as Class 1 recall devices were the Prizm 2 DR, Model 1861 (manufactured on or before April 16, 2002) the Contak Renewal, Model H135 (manufactured on or before August 26, 2004), and the Contak Renewal 2, Model H155 (manufactured on or before August 26, 2004). The FDA stated in its recall notice, that:

> "... these devices can develop an internal short circuit when attempting to deliver an electrical shock to the heart, preventing the treatment of abnormal heart rhythms. The problem is caused by deterioration of electrical insulation in the device and can only be detected after the device has already malfunctioned. The device does not give any sign of impending failure and there is no test that predicts whether the device will fail".

31. In its July 1, 2005 communication, the FDA classified as a Class 2 recall the Ventak Prizm AVT, the Vitality AVT and the Renewal AVT models of devices. The FDA advised that these devices were subject to a memory error which, if it occurred, could limit available therapy. It was stated that this defect was detectable by medical evaluation of the device and subsequent reprogramming. Guidant was noted to be developing additional non-invasive

software solutions for the problem, expected to be available by the end of 2005.

32. In its July 1, 2005 recall notice, Guidant's notification regarding the Contak Renewlal 3 and 4, Renewal 3 and 4 AVT and Renewal RF models of devices were classified as a Class 2 recall. The FDA noted that these devices were prone to a component failure which, if it occurred, might limit available therapy. A magnetic switch in these devices may become stuck in the closed position (called "latching"), which can limit available therapy.

33. On July 18, 2005, Guidant notified physicians that 9 of its pacemaker models, made between 1997 and 2000, might require replacement. It estimated that 28,000 of these devices remained implanted world-wide.

34. Guidant advised that the pacemaker defect related to the degeneration of a hermetic sealing component, resulting in higher than normal moisture within the device and the risk of failure as a result.

35. On July 22, 2005, the FDA notified healthcare providers and patients that it had classified Guidant's notification relating to the pacemakers as a Class 1 recall. The FDA noted that a defective seal within the device allowed moisture to affect the electronic circuits, which had the potential to prevent delivery of pacing entirely, to provide pacing at rates other than those which

the device had been programmed to provide for the patient, or other unexpected, idiosyncratic device behaviors. Failure of the device, the FDA noted, could occur without warning, and if it did occur, could lead to loss of consciousness, heart failure or death. The pacemaker models involved in this Class 1 recall are as described in paragraph 18.

36. In this recall notice relating to the defective Guidant pacemakers, the FDA noted that, while Guidant had provided information to physicians about ways to identify leak related malfunctions, it is not aware of any tests that will show if an apparently normally functioning pacemaker is likely to fail in the future.

37. On July 25, 2005, Health Canada endorsed the recommendation of Guidant on July 18, 2005, that patients with any of its recalled pacemakers, and their treating physicians, should consider replacing their devices for pacemaker dependent patients.

DUTY OF CARE

38. The plaintiff states and the fact is that AICD's, CRT-D's and pacemakers are extremely high risk devices. They are implanted in patients with a history of poor blood circulation, progressive heart failure and dangerously slow, dangerously fast or unsynchronized heart rhythms, all of which make the patients likely to experience irreversible health consequences or death

should the device fail. For these patients, having an unreliable cardiac rhythm management device, which may fail to deliver therapy at any time, is like having implanted a ticking time bomb.

39. If the nature of the defect is such that life saving therapy may be altered or eliminated, many of these device patients, after proper, informed medical advice, will properly elect to protect themselves, mitigate their damages and have their devices explanted and replaced. For those patients who elect not to have their devices explanted and replaced, because of serious medical contraindications to the explant surgery, they will continue to be exposed to increased risk of irreversible adverse health consequences or death, as well as the attendant increased anxiety and mental suffering.

40. As a result, the defendants owed a duty of care to Bruce and other Class 1 members to:

a) ensure that these devices were fit for their intended purposes;

b) conduct pre-market research and development to exacting standards, consistent with the devastating consequences of device failure;

c) ensure that these devices are designed to be safe and effective throughout the life of the device;

d) manufacture these devices in such a manner, and with such materials, that these devices will be safe and effective;

e) market these devices in a responsible manner, advising patients and treating physicians of all known inherent defects;

f) conduct rigorous post-market surveillance, investigate all adverse events fully, and report all adverse events in an accurate, timely and objective manner;

g) warn patients and all treating physicians, in an accurate, timely and objective manner, about known defects and risks of malfunction, and to recall all devices which are prone to failure.

ALLEGATIONS OF NEGLIGENCE

41. The plaintiff states that his damages were caused by the negligence of the defendants, as more particularly set out below.

Negligent Pre-Market Research Development, Design and Testing

42. Prior to the introduction of these defective devices into the Canadian market, the defendants negligently conducted pre-market research and development, design and testing. Particulars of this negligence are as follows:

a) they failed to design and conduct research, including bench testing, animal and clinical studies, to ascertain whether these devices were

safe and effective, and would deliver the therapy that was required when required;

b) they failed to conduct adequate testing, or perform adequate clinical studies, to ascertain whether the device would be safe and effective over the medium to long term life of the device;

c) they failed to test, adequately or at all, the insulating materials to ascertain whether they were prone to degradation over the medium to long term;

d) in light of insulation degradation and failures in its prior devices, the defendants failed to adequately test for the causes of the insulation, degradation and failure, prior to introducing device modifications;

e) they failed to interpret or report data from pre-market testing in an accurate and objective manner to the FDA and Health Canada;

f) they failed to conduct adequate testing which would have predicted the device defects;

g) they failed to conduct testing in accordance with good laboratory practice and relevant International Organization for Standardization (ISO) standards;

h) they knew or should have known that the insulation and seals used in their devices were prone to degradation over the medium to long term life of the device, and would unreasonably increase the risks of device failure.

Negligent Manufacture

43. The plaintiff states and the fact is that the recalled devices were negligently manufactured by the defendants, particulars of which are as follows:

a) they were not fit for the purpose for which they were intended;

b) they were manufactured in a manner which would make the device more prone to electrical faults or failure;

c) they failed to ensure that the devices were not dangerous to patients;

d) they failed to manufacture, or purchase from suppliers, insulation and seals which would not be prone to degradation.

Negligent Distribution and Sale

44. The plaintiff states and the fact is that the defendants negligently distributed and sold these devices, particulars of which are as follows:

a) they failed to disclose sufficient information relating to device safety and efficacy to regulators, patients and treating physicians;

b) they continued to sell these devices in the Canadian market following regulatory approval, notwithstanding receipt of further negative data from post-market testing and adverse event reports from the clinical use of these devices;

c) they failed to perform, adequately or at all, trend analysis to monitor the post-market performance of these devices;

d) they failed to investigate, adequately or at all, adverse event reports;

e) they failed to report, adequately or at all, in a fair, objective and unbiased manner, the results of post-market adverse event investigations;

f) they failed to report adverse events to the regulators and to the medical and scientific community in a timely, accurate and objective manner;

g) they engaged in conduct which favoured their commercial interests over patient safety;

h) they delayed reporting adverse events to regulators, in an attempt to forestall regulatory scrutiny of the safety and efficacy of these devices;

i) they made representations to regulators regarding the safety and efficacy of these devices when they knew or should have known that these representations were false, unsupported or unsupportable.

FAILURE TO WARN AND FAILURE TO RECALL

45. The plaintiff states and the fact is that the defendants were negligent in failing to warn and failing to recall in a timely manner, particulars of which are as follows:

a) they failed to monitor, adequately or at all, the device performance of the general market distribution;

b) they failed to train, instruct, and supervise their employees in rigorous monitoring of the clinical performance of these devices;

c) they failed to adequately respond after becoming aware of mounting evidence of unacceptable clinical performance and failure of its devices, and after becoming aware that the device defects were the very same defects which had caused the recall or withdrawal from market of prior devices;

d) they delayed initiating a recall until there was no alternative whatsoever, thereby endangering the health and safety of device patients.

DAMAGES

46. As a result of the negligence of the defendants, Bruce and other class members, particularly those with devices involved in the Class 1 recalls, have been placed by the defendant in an impossible position. They or their insurers paid a premium price for their devices, relying on the defendants' representations that these devices were safe and effective, would operate over a long implant life, and in a highly reliable manner consistent with the expectations of a premium product. Guidant and its regulators have now advised patients that their devices are prone to failure, that there is no test that can predict which device will fail and when, and that, should the device fail, patients will face a probability of death.

47. Accordingly, class members will elect, or they will already have decided, to have their devices explanted, in which case they will experience or will already have experienced pain and suffering, as well as exposure to the risks involved in the operation. Alternatively, they will elect, or will already have decided, *not* to have their devices explanted, in which case they will experience or will already have experienced emotional distress and anxiety, as well as the increased risk involved in retaining a defective recalled device that can lead to death.

48. Bruce and other class members will also suffer or will already have suffered special damages, losses and expenses, including medical, hospital and other expenses related to the diagnosis, treatment and monitoring of the performance of their devices.

Monitoring

49. As a result of the negligent conduct of the defendants, Bruce and other class members have been exposed to an increased risk of failure of their devices. For those class members with devices affected by the Class 1 recalls, failure of their devices will probably entail death or severe, irreversible health consequences. As a result of the greatly increased risks of these devices, class members claim the benefit of notification that they have a recalled

device, and claim the benefit of a monitoring program, funded by the defendants but at arm's length, to study the mechanisms of failure of these devices, and to test for and attempt to predict potential device failure.

Punitive, Aggravated and Exemplary Damages

50. Guidant, by June of 2003 at the latest, knew or should have known what the duties and responsibilities of a responsible device manufacturer were in regard to defective products. In June 2003, Guidant's wholly owned subsidiary Endovascular Technologies, Inc. agreed to plead guilty to criminal charges in relation to selling misbranded medical devices, and failing to report adverse events to the FDA, in relation to the Ancure Endograft System, released in September, 1999, and withdrawn from the market place in March, 2001. Guidant's Endovascular Technologies subsidiary became aware of reports of malfunctions involving the delivery system of the device (including reports involving serious injury or death), but such reports were concealed from patients, physicians, regulators and the public.

51. By mid 2002 at the latest, Guidant was aware of defects in its AICD's which increased the risk of device failure, and which could result in serious injury or death. It attempted to address the device defects, yet for 3 years continued to sell the defective devices and failed to notify patients, treating physicians or regulators about these defects. It only made a limited notification in May,

2005, after it became aware that the New York Times intended to publish an investigative report on the death of a patient with a Ventak Prizm 2 DR Model 1861 AICD.

52. Further, it has only been as a result of intense regulatory scrutiny that Guidant has made notifications regarding other models of AICD's, CRT-Ds and pacemakers. Details of when Guidant first became aware of defects in these devices are known only to the defendants.

53. The plaintiff states and the fact is that the AICD market is rapidly expanding and highly profitable, and Guidant and its competitors fiercely compete to increase their share of this rapidly emerging and profitable market.

54. The plaintiff states and the fact is that the defendants, in not notifying the patients, treating physicians, and regulators about the defects and dangers in its devices, exposed class members to a greatly increased risk of serious injury or death, preferring profit to patient safety. In so doing, the plaintiff states that the defendants acted in a callous and high-handed manner, and that that conduct merits a significant award of punitive, aggravated and exemplary damages.

Damages of Provincial Health Insurers

55. As a result of the defective devices that had been implanted, many class members will, in an attempt to mitigate their damages, have these devices explanted. They will seek further medical advice, visit their cardiologists and electrophysiologists more frequently, and require more diagnostic testing. The provincial health insurers will be required to pay for additional medical treatment, monitoring costs, costs of explant re-operation, increased costs as a result of surgical complications, and the costs of the replacement device.

56. The provincial health insurers have paid for past insured services and will be required to pay for extensive and costly future insured services.

57. The Multi-Center Automatic Defibrillator Implantation Trial II, a scientific study of ICD therapies sponsored by Guidant ("MADIT-II"), addressed in part the costs of explantation and replacement of an AICD. MADIT-II reported in April, 2004, that the "[c]ost of the initial hospitalization for implantation ($23,000.00) plus device [AICD] ($25,000.00) was estimated at $48,000.00 [in the U.S.A.]." MADIT-II conservatively assumed that AICD generator replacement would occur every 7 years (notwithstanding the manufacturer's claim that the AICD generators are replaced every 11 years) and that the average cost of AICD generator replacement is $21,742.00 (exclusive of any medical costs arising from complications). MADIT-II also noted additional costs relative to monitoring and follow-up after implantation of an AICD.

RELEVANT STATUTES REGULATIONS AND GUIDELINES

58. The plaintiff pleads and relies upon the following:

- *Sale of Goods Act*, R.S.O. 1990, c.S.1;
- The *Class Proceedings Act,* S.O. 1992, c. C.6;
- The *Negligence Act*, R.S.O. 1990, c. N.1;
- *Trustee Act,* R.S.O. 1990, C.T.23 as amended;
- The *Food and Drugs Act,* R.S.C. 1985, c. F-27, as amended, and Regulations made pursuant thereto;
- ISO standards 5841, 10993, 14283, and 11318;
- *Health Insurance Act*, R.S.O. 1990 c. H.6;
- *Family Law Act*, R.S.O. 1990, c. F.3.

REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO

59. The plaintiff pleads that this action has a real and substantial connection with Ontario because, among other things:

a) the defendant, Guidant Canada, has its head office in Markham, Ontario;

b) the defendants carry on business in Ontario and elsewhere in Canada;

c) the defendants market their products in Ontario and elsewhere in Canada;

d) the defendants made their regulatory submissions through their Guidant Canada subsidiary to Health Canada in Ottawa;

e) the defendants were required to report post-market surveillance and adverse events through its Guidant Canada office to Health Canada in Ottawa;

f) the plaintiff's damages were sustained in Ontario;

g) a substantial portion of members of the putative class reside in Ontario

SERVICE OF THIS STATEMENT OF CLAIM OUTSIDE OF ONTARIO

60. This statement of claim may be served without court order outside Ontario, Canada, in that the proceeding against the defendants consists of claims:

(a) in respect of a contract made in Ontario (Rule 17.02 (f));

(b) in respect of a tort committed in Ontario (Rule 17.02(g));

(c) in respect of damage sustained in Ontario arising from a tort or breach of contract, wherever committed (Rule 17.02(h));

(d) against a person outside Ontario who is a necessary or proper party to this proceeding properly brought against another person served in Ontario (Rule 17.02(o)); and

(e) against a person carrying on business in Ontario (Rule 17.02(p)).

PLACE OF TRIAL

61. The plaintiffs propose that this action be tried at Toronto, Ontario, Canada.

Date of Issue:

August 22, 2005

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05-CV-295630CP

HERON et al
Plaintiff

and

GUIDANT CORPORATION et al
Defendants

Court File No:

Ontario
SUPERIOR COURT OF JUSTICE

Proceeding commenced at Toronto

STATEMENT OF CLAIM

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