STATE OF MAINE
KENNEBEC, SS.

SUPERIOR COURT
CIVIL ACTION
DOCKET NO. CV-07-

STATE OF MAINE, Plaintiff, v. GUIDANT CORPORATION, CARDIAC PACEMAKERS, INC., and GUIDANT SALES CORPORATION Defendants.	)	COMPLAINT

INTRODUCTION

1. The State brings this action against Guidant Corporation, Cardiac Pacemakers, Inc. and Guidant Sales Corporation, hereinafter collectively "Defendants", pursuant to the Maine Unfair Trade Practices Act ("MUTPA"), 5 M.R.S.A. §§ 207 and 209 seeking permanent injunctive relief, restitution, civil penalties, costs and attorney's fees.

PARTIES

2. Plaintiff, State of Maine, is a sovereign state and brings this action by and through its Attorney General, G. Steven Rowe, pursuant to 5 M.R.S.A. §§191 and 209 and the powers vested in him by common law.

3. Defendants Guidant Corporation and Guidant Sales Corporation are Indiana corporations. Cardiac Pacemakers is a Minnesota corporation. Defendants regularly conduct business in the State of Maine.

JURISDICTION

4. This Court has jurisdiction over this action pursuant to 4 M.R.S.A. § 105 and 5 M.R.S.A. § 209.

STATEMENT OF CASE

5. Guidant is one of the world's largest manufacturers of implantable cardioverter defibrillators (ICDs).

6. An ICD is a medical device surgically implanted in a patient's chest to monitor for abnormal heart rhythms and if necessary, to deliver an electric shock to restore a normal rhythm. An ICD works as either a pacemaker to normalize the heart's rhythm or as a defibrillator to deliver an electrical shock to the heart muscle so that the heart returns to a normal beating rhythm. If an ICD fails to deliver a shock when needed, and the heart's normal rhythm is thus not restored, the patient could die.

7. Defendants manufactured and sold a specific implantable cardioverter defibrillator known as the Ventak Prizm 2 DR Model 1861 (Prism 1861 defibrillator or device) prior and subsequent to February 2002.

8. In February of 2002, Guidant discovered a problem in the device's design which in

some cases caused an electrical short. The Prizm's polyimide insulation could degrade and because a positively charged feed through wire was placed too close to a negatively charged backfill tube header a short circuit (arcing) could, and in fact sometimes did, occur when the Prizm should have delivered a life saving shock. This rendered the device functionally useless for its intended purpose. The device's failure to work properly could lead to serious injury or death to the patient.

9. In an attempt to prevent this problem from occurring, Guidant made design changes to the Prizm 1861 defibrillator in April 2002 and again in November 2002. Notwithstanding these design changes, Defendants wrongfully continued to market and sell devices from its inventory which had not had the April and November design changes (the "fix") incorporated.

10. Defendants further failed to notify the public, including doctors and patients, of the defect and the design changes made to correct it. Defendants did not even distinguish between the devices manufactured before the fix and those manufactured after the fix, and continued to call all of the devices, regardless of when manufactured, the Ventak Prizm 2 DR Model 1861.

11. Defendants did not disclose the defect and the fix until May 23, 2005, when they learned that the New York Times was planning to publicly disclose the defect, the non-disclosure of the defect by Defendants and that Defendants had continued to sell devices that did not have the fix incorporated into them even after the fix had been made.

12. Defendants continued to sell unmodified devices out of existing inventory without disclosing that the Prizm had been modified until July 2005. Approximately 4,000 such devices manufactured before April 2002, were sold after the fix had been made but before Defendants stopped selling such units.

13. Prescribing physicians and unknowing patients were not formally notified of the defect until June 17, 2005, when the FDA issued a nationwide notification that the Defendants had recalled the Prism 1861 defibrillators manufactured before April 16, 2002.

CAUSE OF ACTION

14. Plaintiff adopts, incorporates herein and re-alleges paragraphs 1 through 13 as if fully set forth below.

15. Concealment of the defect in the devices from physicians and patients and continuing the sale of the defective devices constituted a danger to the public and an unfair and deceptive trade practice pursuant to 5 M.R.S.A. § 207.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff request that a judgment and order be entered that:

A. Permanently enjoins Defendants from engaging in the deceptive, fraudulent and unlawful practices in violation of 5 M.R.S.A. § 207.

B. Permanently enjoins Defendants from marketing or selling Ventak Prism ZDR Model 1861 manufactured prior to February 2002.

C. Order Defendants to pay civil penalties for each willful violation of 5 M.R.S.A. § 207.

D. Order Defendants to pay the Plaintiff's cost of suit including its attorneys' fees.

E. Grant all other Relief as the Court deems appropriate.

Dated: August 30, 2007

Respectfully submitted,

G. STEVEN ROWE

ATTORNEY GENERAL

Linda J. Conti, Me. Bar No. 3638
Assistant Attorney General
Office of the Attorney General
6 State House Station
Augusta, ME 04333-0006
Tel. (207) 626-8591

STATE OF MAINE
KENNEBEC, SS.

SUPERIOR COURT
CIVIL ACTION
DOCKET NO. CV-07-

STATE OF MAINE ex rel G. STEVEN ROWE, Attorney General for the State of Maine	)	
Plaintiff,	)	STIPULATED GENERAL JUDGMENT
v.	)	
GUIDANT CORPORATION, *et al.*	)	
Defendant.	)	

Plaintiff, State of Maine, acting by and through Attorney General G. Steven Rowe has brought this action pursuant to Maine Unfair Trade Practices Act, 5 M.R.S.A. § 207 ("the Act"), having filed a Complaint against the Defendant Guidant Corporation and the parties having consented to the entry of this Stipulated General Judgment (hereinafter referred to as "Judgment") for the purpose of settlement only, without trial of any issue of fact or law, NOW THEREFORE, upon the consent of the parties hereto

IT IS HEREBY ORDERED, ADJUDGED AND DECREED AS FOLLOWS:

I. FINDINGS

1. This Court has jurisdiction over the subject matter of this lawsuit and over all parties.

2. The terms of this Judgment shall be governed by the laws of the State of Maine.

3. Entry of this Judgment is in the public interest and reflects a negotiated agreement among the parties.

4. The parties have agreed to resolve the issues raised by the matters investigated by the Attorneys General by entering into this Judgment. GUIDANT is entering into this Judgment solely for the purpose of settlement and nothing contained herein may be taken as or construed to be an admission or concession of any violation of any statute, law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which GUIDANT expressly denies. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing, nor shall any part of this Judgment be construed or used as a waiver or limitation of any defense otherwise available to GUIDANT or of GUIDANT's right to defend itself from or against any private individual or class claims or suits. No part of this Judgment shall create a private cause of action or confer any right to any third-party for violation of any federal or state statute to enforce the terms of this Judgment, or for any other purpose whatsoever, except that either GUIDANT or a Settling State may file an action to enforce the terms of this Judgment.

5. This Judgment is applicable to GUIDANT and to GUIDANT's agents, employees, representatives, assignees, and successors in interest who have actual or constructive notice of its provisions (hereinafter collectively "Enjoined Persons").

II. DEFINITIONS

6. The following definitions shall be used in construing this Judgment:

A. "AdvaMed" means the Advanced Medical Technology Association (AdvaMed).

B. "Applicable Standard" means the AdvaMed standard entitled Industry Guidance: Uniform Reporting of Clinical Performance of Pulse Generators, dated January 30, 2007.

C. "Covered ICDs" mean the following ICDs: (1) VENTAK PRIZM® 2 DR Model 1861 devices; (2) CONTAK RENEWAL® Model H135 devices; and (3) CONTAK RENEWAL® 2 Model H155 devices.

D. "Discontinued ICD" means an ICD that is no longer manufactured or sold by GUIDANT and for which the estimate of active implants is believed to be fewer than 200 based on the best information available to GUIDANT.

E. "Effective Date" shall mean the date which is five (5) business days after the last of the following conditions is satisfied: (1) GUIDANT receives a copy of this Judgment, duly executed by GUIDANT and by each of the Settling States and (2) this Judgment is entered by a court of competent jurisdiction in each and every one of the Settling States.

F. "FDA" means the U.S. Food and Drug Administration.

G. "FDA's Guidances for Industry" means documents published by the FDA that represent the FDA's current recommendations on a topic.

H. "FDCA" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as the same may be amended.

I. Unless otherwise specified, "GUIDANT" means Guidant Corporation, Cardiac Pacemakers, Inc., and Guidant Sales Corporation, and their successors and assigns.

J. Unless otherwise specified, "Implantable Cardioverter Defibrillator" or "ICD" means a device implanted in the chest that was approved by the FDA at any time from and after January 2000 that monitors for and, if necessary corrects, certain episodes of an abnormal heart rhythm.

K. Unless otherwise specified, "Information" means available information which: (1) a patient may rely on or consider in evaluating or making a decision about his or her treatment; or (2) a physician or a hospital may rely on or consider in evaluating, recommending, or formulating a treatment for a patient.

L. "Multistate Executive Committee" means the Attorneys General of Arizona, California, Florida, Illinois, Oregon, and Vermont.

M. "New ICD" means an ICD, including a new model of an existing ICD family that is marketed and sold by GUIDANT for the first time at any time after September 8, 2005.

N. "Privilege" means a privilege that exists under the laws or rules in the state, or that involves specific patient information. Privileged information shall be redacted where feasible to make the information non-Privileged.

O. "Settling State" or "State" means the states of Alaska, Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Hawaii, Idaho, Illinois, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, and Wyoming.

P. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Attorneys General have conducted their investigations.[1]

Q. "Subject Matter of this Judgment" shall mean the Settling States' Attorneys Generals' investigations and inquiries under the State Consumer Protection Laws concerning GUIDANT's marketing and sales of ICDs, as defined in Paragraph J, above.

R. "Warranty Supplement Program" means the supplemental warranty program announced by GUIDANT in June 2005 and December 2005 to provide, subject to certain conditions, replacement devices and reimbursement of certain

[1] ALASKA Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq*; ARIZONA - Consumer Fraud Act, Ariz. Rev. Stat. §44-1521, *et. seq.*; ARKANSAS - Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101 *et seq.*; CALIFORNIA Business and Professions Code § 17200 *et seq.* 17500 *et seq.*; CONNECTICUT - Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110b *et seq*; DISTRICT OF COLUMBIA - District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901 *et seq.*; FLORIDA -Deceptive and Unfair Trade Practices Act, Fla. Stat. Ch.501.201 et seq. - HAWAII- Uniform Deceptive Trade Practice Act, Hawaii Rev. Stat. Chpt. 481A and Haw. Rev. Stat. sect. 480-2; IDAHO - Consumer Protection Act, Idaho Code § 48-601 *et seq.*; ILLINOIS - Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.* (2002); KANSAS - Kansas Consumer Protection Act: K.S.A. 50-623 et seq; KENTUCKY - Consumer Protection Statute, KRS 367.170 *et seq*; LOUISIANA - Unfair Trade Practices and Consumer Protection Law, LSA-R.S. 51:1401 *et seq.*; MAINE - Unfair Trade Practices Act, 5 M.R.S.A. section 205-A *et.* seq.; MARYLAND - Consumer Protection Act, Maryland Commercial Law Code Annotated § 13-101 *et seq.*; MASSACHUSETTS - Consumer Protection Act, M.G.L. c. 93A *et seq.*; MICHIGAN - Michigan Consumer Protection Act, MCL 445.901 et seq. ; MISSISSIPPI - Miss. Code Ann. § 75-24-1 et seq., (1972) as amended ; MISSOURI -MISSOURI - Merchandising Practices Act, Mo. Rev. Stat. Sections 407.020 and 407.100; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW JERSEY -New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq ; NEW MEXICO - Unfair Practices Act" NMSA 1978, § 57-12-1 *et seq.* (1967); NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1 *et seq.*; NORTH DAKOTA - Consumer Fraud and Unlawful Credit Practices Act, N.D.C.C. § 51-15-01 *et seq.* ; OHIO - Consumer Sales Practices Act, R.C. § 1345.01 *et seq.*; OREGON - Unlawful Trade Practices Act, ORS 646.605 to 646.656; PENNSYLVANIA - Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 *et seq.*; SOUTH CAROLINA - Unfair Trade Practices Act, S.C. Code Ann. Sections 39-5-10 *et seq.*; TENNESSEE - Consumer Protection Act, Tenn. Code Ann. § 47-18-101 *et seq.*, (1977); TEXAS - Deceptive Trade Practices and Consumer Protection Act, Tex. Bus. And Com. Code § 17.41 *et seq.*, (Vernon 2002); VERMONT - Consumer Fraud Act, 9 V.S.A. § 2451 *et seq.*; VIRGINIA - Virginia Consumer Protection Act, Va. Code § 59.1-196 *et seq.*; WASHINGTON - Washington Consumer Protection Act – R.C.W. 1986 § 19.86.010 *et seq.*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations); WYOMING - Wyoming Consumer Protection Act - W.S. § 40-12-101 et seq.

unreimbursed medical expenses incurred by a patient in connection with the replacement of certain ICDs covered by the Warranty Supplement Program.

III. COMPLIANCE PROVISIONS

PERMANENT INJUNCTION

7. For a period of no less than five (5) years from the Effective Date, GUIDANT shall establish an Independent Patient Safety Advisory Board, beginning within one hundred twenty (120) days following the Effective Date, to evaluate data concerning ICD performance and risk assessment data. The Patient Safety Advisory Board shall include independent experts whose expertise includes cardiac electrophysiology, engineering, statistics, risk management, and bioethics. At least one member of the board will represent the views of patients. The board's function shall be linked to GUIDANT by the Patient Safety Officer as set forth in paragraph 8, below. GUIDANT may reasonably compensate members of the board at a rate that is normal and customary in the market for persons performing similar services.

8. Beginning no later than one hundred twenty (120) days following the Effective Date, and for a period of no less than five (5) years from the date of employment, GUIDANT shall employ a Patient Safety Officer who shall hold the position of a vice president and be a physician and who shall have as a primary responsibility, with respect to ICDs, advancing patient safety and whose job description shall include participation in performance analysis, related health hazard analysis, internal product performance communications, and external product performance communication policies and procedures, including those related to product

improvements and emerging health safety issues. The Patient Safety Officer shall act as a liaison with the Patient Safety Advisory Board. The Patient Safety Officer shall have routine access to the highest-ranking executive officer at Guidant's Cardiac Rhythm Management Business or the successor group or entity responsible for the Cardiac Rhythm Management Business in order to perform the duties of this position. The Patient Safety Officer shall have no conflicts of interest between the performance of any other job duties at GUIDANT and the duties required of the Patient Safety Officer.

9. For a period of no less than five (5) years from the Effective Date, and subject to paragraph 10, GUIDANT shall clearly and conspicuously disclose and disseminate to the public in an easily accessible form, the following product performance Information for ICDs no less often than once per calendar quarter:

a. Worldwide failure data, including data on ICD returns confirmed to have malfunctioned while implanted and in service, stratified according to the following:

i. whether the confirmed malfunctions occurred in a manner that did or did not compromise pacing or defibrillation therapy;

ii. failure pattern (root cause);

iii. whether modifications have been made to address the failure pattern; and

iv. whether safety advisories have been issued for such product families.

b. United States data on survival probability estimates:

i. for ICD product families that have a minimum of 10,000 implant months and an active population of 200 devices remaining in the United States; or

ii. in the event that AdvaMed modifies the Applicable Standard, for ICD product families having a minimum number of implant months and an

active population of devices that comply with such modified Applicable Standard;

c. Current information related to any safety advisory classified by the FDA as a Class I or Class II recall:

i. (A) for which there is an estimated active United States population of at least 200 devices; or

(B) in the event that AdvaMed modifies the Applicable Standard, for which there is an estimated active United States population equal to or greater than the population specified in such modified Applicable Standard; *provided* that, in the event that there occurs a change in AdvaMed standards that GUIDANT believes would require the adoption of practices that differ from or conflict with the practices prescribed by this paragraph 9, GUIDANT shall notify the Multistate Executive Committee (acting on behalf of the Attorneys General) of the new standards, requirements or needs, and request that the Multistate Executive Committee (on behalf of the Attorneys General) consent in writing to modify this paragraph to the extent necessary to substitute such practices for the practices prescribed by this paragraph 9, which consent shall not be unreasonably withheld nor unreasonably delayed; and

ii. with respect to which GUIDANT shall display, in a clear and conspicuous manner, a search engine on its website that permits a patient to search for and identify safety advisories that have been issued since January 2005

with respect to devices implanted in such patient by inputting the model and serial number of the device in the search engine; and

iii. Guidant shall make public safety advisories as soon as it can reasonably do so after it notifies patients' physicians.

d. GUIDANT shall provide links on its website to its Medical Device Reporting ("MDR") reports maintained by the FDA that pertain to ICDs.

e. Notwithstanding anything to the contrary in this paragraph 9, if GUIDANT makes a modification to address a failure pattern resulting in loss of therapy, GUIDANT shall post on its website the existence of such modification in the next quarterly product performance report, but in no event later than thirty (30) days after such modification is implemented.

10. GUIDANT shall not be required to make the disclosures described in paragraph 9:

a. with respect to any New ICD until the first annual anniversary of the first commercial sale of such New ICD by GUIDANT, to permit GUIDANT sufficient time to collect meaningful data concerning such New ICD; and

b. at all with respect to any Discontinued ICDs; and

c. with respect to any country or other jurisdiction whose laws prohibit GUIDANT from disclosing such information with respect to citizens or residents of, or medical devices sold or located in, that country or jurisdiction; and

d. with respect to advisories classified by the FDA as Class III recalls.

11. For a period of no less than seven (7) years from the Effective Date, GUIDANT shall solicit the return of out-of-service ICDs to assist in gathering information provided for in paragraph 9, above, to the extent permitted by (a) the law of the jurisdiction in which the patient

resides, is domiciled and/or can be found; or (b) the law of jurisdiction where the device return is solicited.

12. For a period of no less than seven (7) years from the Effective Date, GUIDANT shall keep comprehensive, organized, accessible and sustainable data system(s) to capture and maintain certain Information concerning all U.S.-distributed ICDs, which Information shall include:

a. the device's lot number, batch number, model number, or serial number, or other identifier necessary to provide for effective tracking of the device;

b. the date the device was shipped by GUIDANT;

c. the date the device was implanted in the patient; and,

d. if applicable and to the extent available or known to GUIDANT, the date the device was explanted, or the date of the patient's death, or the date the device was returned to GUIDANT, permanently retired from use or otherwise permanently disposed of.

13. Nothing in this Judgment shall require GUIDANT to:

a. take an action that is prohibited by the FDCA or any applicable federal law or regulation, or by the FDA; or

b. fail to take an action that is required by the FDCA or any applicable federal law or regulation, or by the FDA.

14. If, after the Effective Date of this Judgment, the United States, a State, or any foreign government or governmental agency enacts or promulgates legislation, rules or regulations or issues new regulatory requirements or FDA's Guidances for Industry with respect to matters governed by this Judgment that conflict with any provision of this Judgment,

GUIDANT shall notify the Attorneys General (or the Attorney General of the affected State) of its intention to comply with the newly enacted, promulgated or issued legislation, rule, regulation, requirements or FDA Guidances for Industry, and the Attorneys General (or the Attorney General of the affected State) shall consent to the modification of such provision to the extent necessary to eliminate a conflict if GUIDANT cannot comply with both such legislation, rule, regulation, requirements or FDA Guidances for Industry and the applicable provision of this Judgment.

IV. SETTLEMENT FUND AND OTHER RELIEF

15. GUIDANT shall extend the existing Warranty Supplement Program for patient costs directly associated with the cost of repair or re-programming of the Covered ICDs to a date ending no earlier than six months from the Effective Date.

16. One million dollars ($1,000,000) of the payment referenced in paragraph 17 below that GUIDANT makes to the States, shall be set aside by the States to cover, as much as possible, direct patient costs that exceed the $2,500.00 Warranty Supplement Program cap, for those patients who request reimbursement for such payments and who are residents of Settling States. Guidant shall make this one million dollar payment to the Attorney General of the State of Oregon to be deposited in the Attorney General's Client Trust Account. The Oregon Attorney General shall make payments from this amount as directed by the Multistate Executive Committee. These funds shall be distributed within twelve (12) months of the Effective Date. Any residue shall be equally distributed among the Settling States. Upon being provided with appropriate waivers by the patients, and upon request by the Attorneys General, Guidant shall provide the signatory Attorney General, within thirty (30) days of the request, records relating to the application for refunds under the Warranty Supplement Program by patients residing in the

signatory Attorney General's Settling State, including payments made; partial payments made and the reason why full payments were not made; and, denials of refunds and the reason why the refunds were denied. Regardless of whether requested, Guidant shall give notice to the Attorney General of the state in which the patient resides no later than sixty (60) days after it has issued a final denial for payment of portions of a patient's claim for unreimbursed medical expenses that exceed $2,500 under the Unreimbursed Medical Expenses program related to the Warranty Supplement Program available for the Covered ICDs. As designated and at the sole discretion of the Multistate Executive Committee, the money set aside by this paragraph shall be divided and paid to specific patients, who are residents of Settling States, either in full or on a pro rata basis, for direct patient costs in excess of $2,500.

17. Within forty-five (45) days of the Effective Date of this Judgment, GUIDANT shall pay a total amount of Sixteen Million Seven Hundred Fifty Thousand Dollars ($16,750,000) to be divided and paid by GUIDANT directly to each Settling State in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. Said payment shall be used by the States for attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, the consumer protection enforcement fund, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for other uses permitted by state law, at the sole discretion of each signatory Attorney General.

18. Within one year of the Effective Date, GUIDANT shall provide the Multistate Executive Committee with a report providing the number of individuals who submitted warranty supplement claims under the Warranty Supplement Program; the number of individuals who received any form of warranty consideration under the Warranty Supplement Program; and the

total warranty consideration paid under the Warranty Supplement Program. The Multistate Executive Committee, the Attorneys General, and the Settling States shall maintain the confidentiality of any report submitted pursuant to this paragraph 18, subject to the existing confidentiality agreement between the parties.

V. RELEASE

19. By its execution of this Judgment, each Settling State releases Guidant and all of its past and present parents, subsidiaries, affiliates, predecessors and successors (collectively, the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, fines, costs, and penalties on behalf of the Settling States under the consumer protection statutes cited in footnote 1 arising from the allegations that are the Subject Matter of this Judgment that occurred at any time through and including the Effective Date of this Judgment.

20. Notwithstanding any term of this Judgment, any and all of the following are specifically reserved and excluded from the Released Claims as to any entity or person, including Released Parties:

a. Any criminal liability that any person or entity, including Released Parties, has or may have to the State of Maine;

b. Any civil or administrative liability that any person or entity, including Released Parties, has or may have to the State of Maine under any statute, regulation or rule not expressly covered by the release in paragraph 19 above, including but not limited to any and all of the following claims:

i. State or federal antitrust violations;

ii. Reporting practices, including "best price", "average wholesale price" or "wholesale acquisition cost;"

iii. Medicaid violations, including federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program; and,

iv. State false claims violations.

c. Any liability under the Settling States' above-cited consumer protection laws which any person or entity, including Released Parties, has or may have to individual consumers or State program payers of said States, and which have not been specifically enumerated as included here.

VI. NO ADMISSION OF LIABILITY

21. This Judgment does not constitute an admission by GUIDANT for any purpose, of any fact or of a violation of any state or federal law, rule, or regulation, nor does this constitute evidence of any liability, fault, or wrongdoing. GUIDANT enters into this Judgment solely for the purpose of resolving the allegations of the Attorneys General regarding GUIDANT ICDs. GUIDANT does not admit any violation of the Act and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under those laws set out in footnote 1.

22. This Judgment shall not be construed or used as a waiver or any limitation of any defense otherwise available to GUIDANT. This Judgment is made without trial or adjudication of any issue of fact or law or finding of liability of any kind. Nothing in this Judgment, including this paragraph, shall be construed to limit or to restrict GUIDANT's right to use this Judgment to assert and maintain the defenses of *res judicata*, collateral estoppel, payment,

compromise and settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or future legal or administrative action or proceeding.

VII. COMPLIANCE REQUIREMENTS

23. For the purpose of monitoring and investigating compliance with any provision of this Judgment, GUIDANT shall create and maintain business records, policies, processes and standard operating procedures to demonstrate compliance with the terms and provisions of this Judgment. At a minimum, for a period of five (5) years, GUIDANT shall take reasonable steps to:

a. Allow the Attorney General, or any of his or her representatives, reasonable access to GUIDANT's business premises during normal business hours to inspect relevant, non-Privileged and non-work-product records and documents that relate to Guidant's compliance with this Judgment; or

b. If requested, provide such data to the Attorney General or his or her office, and to interview any of the Enjoined Persons on a subject matter relating to compliance with this Judgment, provided that GUIDANT and/or any such Enjoined Person may have counsel present and may assert any legally recognized Privilege during any access, inspection or interview.

c. Any information obtained by the Attorney General or his representative pursuant to this paragraph shall be subject to the existing confidentiality agreement between the parties.

24. For the purpose of monitoring and ensuring compliance, GUIDANT shall for a period of five (5) years from the Effective Date:

a. Maintain copies of all data obtained by Guidant, in both raw and analyzed form, including but not limited to pre-clinical, clinical, post-marketing or other scientific data relating to an ICD, whether or not such data are generated by GUIDANT's own research and development or monitoring, or by a third-party source; and

b. Create and maintain all other documents and records necessary and sufficient to demonstrate full compliance with the terms and provisions of this Judgment.

25. GUIDANT shall notify the Multistate Executive Committee at least five (5) business days after any change in GUIDANT or Boston Scientific Corporation that may affect compliance obligations arising out of this Judgment, including any dissolution of GUIDANT or Boston Scientific Corporation, or any acquisition, merger, or consolidation of GUIDANT or Boston Scientific Corporation.

26. Nothing in this Judgment shall be construed as:

a. relieving GUIDANT of its obligation to comply with all state laws, regulations or rules, or granting permission to engage in any acts or practices prohibited by such law, regulation or rule; or

b. limiting or expanding in any way any right the State may otherwise have to obtain information, documents or testimony from GUIDANT pursuant to any state law, regulation or rule, or any right GUIDANT may otherwise have to oppose any subpoena, civil investigative demand, compulsory process, motion, or other procedure issued, served, filed, or otherwise employed by the State pursuant to any such state law, regulation or rule.

27. In the event that the Multistate Executive Committee, any Attorney General, or any Settling State is served with a freedom of information act or similar request, or with any

subpoena or other legal process, requesting or requiring it to provide or produce any report or information provided by GUIDANT pursuant to paragraph 18 or any information obtained pursuant to paragraph 23 of this Judgment, the Multistate Executive Committee, such Attorney General, and/or such Settling State (as the case may be) shall inform GUIDANT within ten (10) calendar days of receipt of such request, subpoena, or legal process and no less than ten (10) business days before any deadline for responding to such request, subpoena, or legal process, and GUIDANT shall have the right and responsibility in its sole discretion to challenge such request, subpoena or legal process.

VIII. REPRESENTATIONS AND WARRANTIES

28. GUIDANT acknowledges that it is the proper party to this Judgment. GUIDANT warrants and represents that the individual signing this Judgment on behalf of Guidant is doing so in his or her official capacity and is fully authorized by GUIDANT to enter into this Judgment and to legally bind GUIDANT to all of the terms and conditions of this Judgment.

29. The Attorneys General signatory warrants and represents that he or she is signing this Judgment in his or her official capacity, and that he or she is fully authorized by his or her state to enter into this Judgment, including but not limited to the authority to grant the release contained in Paragraphs 19 and 20 of this Judgment, and to legally bind the state to all of the terms and conditions of this Judgment.

IX. ORDER DISTRIBUTION

30. Within sixty (60) days of the Effective Date of this Judgment and for a period of no less than seven (7) years from the Effective Date, GUIDANT shall cause all of its vice presidents or higher corporate officers (regardless of contact with patients, physicians, hospitals, or research institutions), to review a copy of this Judgment. GUIDANT shall also provide a copy

of this Judgment to all of its new vice presidents or higher corporate officers, within thirty (30) days of hiring such person. GUIDANT shall obtain from each person who has received this Judgment an electronic certification acknowledging that he/she reviewed this Judgment. GUIDANT shall maintain such acknowledgement for a minimum of three (3) years from the date each is provided to GUIDANT and shall make them available for inspection and copying upon request of any representative of the Settling States' Attorneys General.

X. DISPUTES REGARDING COMPLIANCE

31. For the purposes of resolving disputes with respect to compliance with this Judgment, should the Attorney General have legally sufficient cause (which shall include, at a minimum, a reasonable basis to believe that Guidant has violated a provision of this Judgment), then the Attorney General shall notify Guidant in writing of the specific objection, identify with particularity the provisions of this Judgment and/or the State Consumer Protection Laws that the practice appears to violate, and give Guidant thirty (30) business days to respond to the notification; provided, however, that the Attorney General may take any action upon notice to Guidant where the Attorney General concludes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

32. Upon receipt of written notice and within the thirty (30) business-day period, Guidant shall provide a good faith written response to the Attorney General's objection. The response shall include an affidavit containing either:

a. A statement explaining why Guidant believes it is in compliance with the Judgment; or

b. A detailed explanation of how the alleged violation[s] occurred; and

i. A statement that the alleged breach has been cured and how it has been cured; or

ii. A statement that the alleged breach cannot be reasonably cured within thirty (30) business days from receipt of the notice, but (1) Guidant has begun to take corrective action to cure the alleged breach; (2) Guidant is pursuing such corrective action with reasonable and due diligence; and (3) Guidant has provided the Attorney General with a detailed and reasonable time table for curing the alleged breach.

33. Nothing herein shall prevent the Attorney General from agreeing in writing to provide Guidant with additional time beyond the thirty (30) business-day period to respond to the notice.

34. Nothing herein shall be construed to exonerate any failure to comply with any provision of this Judgment after the date of entry or to compromise the authority of the Signatory Attorney General to initiate a proceeding for failure to comply. Further, nothing in this subsection shall be construed to limit the authority of the Signatory Attorney General to protect the interests of the State.

35. The Signatory Attorney General represents that he or she will seek enforcement of the provisions of this Judgment with due regard for fairness and, in so doing, shall take into account efforts that Guidant has taken to cure any claimed violation of this Judgment.

XI. ENFORCEMENT

36. Any party to this Judgment may apply to a court of competent jurisdiction at any time for such further orders and directions as are necessary or appropriate for carrying out this

Judgment, including the modification of the injunctive provisions, the enforcement of compliance, and the punishment of violations as permitted by law.

XII. NOTICES

37. Any notices provided pursuant to the requirements of this Judgment shall be deemed given five (5) business days after mailing or one (1) business day after facsimile or e-mail transmission. All such notices shall be in writing and shall be addressed as follows:

To GUIDANT:

Jean Holloway, Esq.
Vice President, Legal
Boston Scientific Corporation
Cardiac Rhythm Management
4100 Hamline Ave North
St. Paul, Minnesota 55112-5798
Tel: 651-582-7501
Fax: 561-582-7400

with a copy to:

Timothy Pratt, Esq.
Shook, Hardy & Bacon L.L.P.
2555 Grand Boulevard
Kansas City, Missouri 64108-2613
Tel: 816-474-6550
Fax: 816-421-5547

To the State of Maine:

Linda J. Conti
Assistant Attorney General
Office of the Attorney General
6 State House Station
Augusta, ME 04333-0006
Tel: (207) 626-8591
Fax: (207) 624-7730

To Multistate Executive Committee or to the Oregon Attorney General:

David Hart, Esq.
Assistant Attorney General
1162 Court Street NE
Salem, OR 97301-4096
Tel: (503) 947-4333
Fax: (503) 378-5017

IT IS SO ADJUDGED AND ORDERED:

DATED this 25th day of September, 2007.

JUSTICE, SUPERIOR COURT

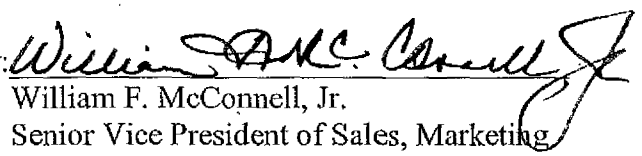
Thompson & Bowie LLP

By: _____
Mark V. Franco Esq., ME Bar # 2967
Three Canal Plaza
PO Box 4630
Portland ME 04112
(207) 774-2500
mfranco@thompsonbowie.com

Attorneys For Guidant

GUIDANT CORPORATION

FOR GUIDANT:

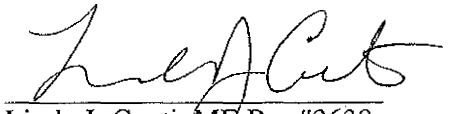
By: 

William F. McConnell, Jr.
Senior Vice President of Sales, Marketing
and Administration
4100 Hamline Ave. North
St. Paul, Minnesota 55112-5798

Date: August 20, 2007

By:_____
William F. McConnell, Jr.
Senior Vice President, Marketing and Administration

FOR THE STATE OF MAINE
G. STEVEN ROWE



Linda J. Conti, ME Bar #3638
Assistant Attorney General
Office of the Attorney General
6 State House Station
Augusta, ME 043330-0006
Phone: (207) 626-8591
Fax: (207) 624-7730
Email: linda.conti@maine.gov