

STATE OF OREGON
MARION COUNTY COURTS
AUG 30 2007
FILED

IN THE CIRCUIT COURT OF THE STATE OF OREGON
FOR THE COUNTY OF MARION

STATE OF OREGON ex rel HARDY
MYERS Attorney General for the State of
Oregon,

Plaintiff,

v.

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

Defendants.

Case No. 07C 19067
STIPULATED GENERAL JUDGMENT

Plaintiff, State of Oregon, acting by and through Attorney General Hardy Myers has brought this action pursuant to ORS 646.632, having filed a Complaint against the Defendants Guidant Corporation, Guidant Sales Corporation, and Cardiac Pacemakers, Inc. 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 Oregon.
3. Entry of this Judgment is in the public interest and reflects a negotiated agreement among the parties.

1 4. The parties have agreed to resolve the issues raised by the matters investigated by the
2 Attorneys General by entering into this Judgment. GUIDANT is entering into this Judgment
3 solely for the purpose of settlement and nothing contained herein may be taken as or construed to
4 be an admission or concession of any violation of any statute, law, rule, or regulation, or of any
5 other matter of fact or law, or of any liability or wrongdoing, all of which GUIDANT expressly
6 denies. No part of this Judgment, including its statements and commitments, shall constitute
7 evidence of any liability, fault, or wrongdoing, nor shall any part of this Judgment be construed
8 or used as a waiver or limitation of any defense otherwise available to GUIDANT or of
9 GUIDANT's right to defend itself from or against any private individual or class claims or suits.
10 No part of this Judgment shall create a private cause of action or confer any right to any third-
11 party for violation of any federal or state statute to enforce the terms of this Judgment, or for any
12 other purpose whatsoever, except that either GUIDANT or a Settling State may file an action to
13 enforce the terms of this Judgment.
14

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

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

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

22 B. "Applicable Standard" means the AdvaMed standard entitled Industry Guidance:
23 Uniform Reporting of Clinical Performance of Pulse Generators, dated January 30, 2007.
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1 C. "Covered ICDs" mean the following ICDs: (1) VENTAK PRIZM® 2 DR Model
2 1861 devices; (2) CONTAK RENEWAL® Model H135 devices; and (3) CONTAK
3 RENEWAL® 2 Model H155 devices.

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

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

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

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

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

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

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

22 K. Unless otherwise specified, "Information" means available information which:
23
24 (1) a patient may rely on or consider in evaluating or making a decision about his or her
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1 treatment; or (2) a physician or a hospital may rely on or consider in evaluating,
2 recommending, or formulating a treatment for a patient.

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

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

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

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

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

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21 ¹ ALASKA Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq.*; ARIZONA - Consumer
22 Fraud Act, Ariz. Rev. Stat. §44-1521, *et seq.*; ARKANSAS - Deceptive Trade Practices Act, Ark. Code Ann. § 4-
23 88-101 *et seq.*; CALIFORNIA Business and Professions Code § 17200 *et seq.* 17500 *et seq.*; CONNECTICUT -
24 Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110b *et seq.*; DISTRICT OF COLUMBIA - District of
25 Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901 *et seq.*; FLORIDA -Deceptive and
26 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 -

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

4 R. "Warranty Supplement Program" means the supplemental warranty program
5 announced by GUIDANT in June 2005 and December 2005 to provide, subject to certain
6 conditions, replacement devices and reimbursement of certain unreimbursed medical
7 expenses incurred by a patient in connection with the replacement of certain ICDs
8 covered by the Warranty Supplement Program.
9

10 III. COMPLIANCE PROVISIONS

11 PERMANENT INJUNCTION

12 7. For a period of no less than five (5) years from the Effective Date, GUIDANT shall
13 establish an Independent Patient Safety Advisory Board, beginning within one hundred twenty
14 (120) days following the Effective Date, to evaluate data concerning ICD performance and risk
15 assessment data. The Patient Safety Advisory Board shall include independent experts whose
16 expertise includes cardiac electrophysiology, engineering, statistics, risk management, and
17 bioethics. At least one member of the board will represent the views of patients. The board's
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20 Miss. Code Ann. § 75-24-1 *et seq.*, (1972) as amended ; MISSOURI -MISSOURI - Merchandising Practices Act,
21 Mo. Rev. Stat. Sections 407.020 and 407.100; MONTANA - Mont. Code Ann. § 30-14-101 *et seq.*; NEVADA -
22 Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903 *et seq.*; NEW JERSEY -New Jersey Consumer
23 Fraud Act, N.J.S.A. 56:8-1 *et seq.*; NEW MEXICO - Unfair Practices Act" NMSA 1978, S 57-12-1 *et seq.* (1967);
24 NORTH CAROLINA - Unfair and Deceptive Trade Practices Act, N.C.G.S. § 75-1.1 *et seq.*; NORTH DAKOTA -
25 Consumer Fraud and Unlawful Credit Practices Act, N.D.C.C. § 51-15-01 *et seq.*; OHIO - Consumer Sales
26 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, 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 *et seq.*; WISCONSIN - Wis. Stat. § 100.18 (Fraudulent Representations);
WYOMING - Wyoming Consumer Protection Act - W.S. § 40-12-101 *et seq.*

1 function shall be linked to GUIDANT by the Patient Safety Officer as set forth in paragraph 8,
2 below. GUIDANT may reasonably compensate members of the board at a rate that is normal
3 and customary in the market for persons performing similar services.

4 8. Beginning no later than one hundred twenty (120) days following the Effective Date, and
5 for a period of no less than five (5) years from the date of employment, GUIDANT shall employ
6 a Patient Safety Officer who shall hold the position of a vice president and be a physician and
7 who shall have as a primary responsibility, with respect to ICDs, advancing patient safety and
8 whose job description shall include participation in performance analysis, related health hazard
9 analysis, internal product performance communications, and external product performance
10 communication policies and procedures, including those related to product improvements and
11 emerging health safety issues. The Patient Safety Officer shall act as a liaison with the Patient
12 Safety Advisory Board. The Patient Safety Officer shall have routine access to the highest-
13 ranking executive officer at Guidant's Cardiac Rhythm Management Business or the successor
14 group or entity responsible for the Cardiac Rhythm Management Business in order to perform
15 the duties of this position. The Patient Safety Officer shall have no conflicts of interest between
16 the performance of any other job duties at GUIDANT and the duties required of the Patient
17 Safety Officer.

18 9. For a period of no less than five (5) years from the Effective Date, and subject to
19 paragraph 10, GUIDANT shall clearly and conspicuously disclose and disseminate to the public
20 in an easily accessible form, the following product performance Information for ICDs no less
21 often than once per calendar quarter:
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- 1 a. Worldwide failure data, including data on ICD returns confirmed to have
2 malfunctioned while implanted and in service, stratified according to the following:
- 3 i. whether the confirmed malfunctions occurred in a manner that did or did not
4 compromise pacing or defibrillation therapy;
 - 5 ii. failure pattern (root cause);
 - 6 iii. whether modifications have been made to address the failure pattern; and
 - 7 iv. whether safety advisories have been issued for such product families.
- 8
- 9 b. United States data on survival probability estimates:
- 10 i. for ICD product families that have a minimum of 10,000 implant months
11 and an active population of 200 devices remaining in the United States; or
 - 12 ii. in the event that AdvaMed modifies the Applicable Standard, for ICD
13 product families having a minimum number of implant months and an
14 active population of devices that comply with such modified Applicable
15 Standard;
- 16
- 17 c. Current information related to any safety advisory classified by the FDA as a
18 Class I or Class II recall:
- 19 i. (A) for which there is an estimated active United States population of
20 at least 200 devices; or
 - 21 (B) in the event that AdvaMed modifies the Applicable Standard, for
22 which there is an estimated active United States population equal to or
23 greater than the population specified in such modified Applicable
24 Standard; provided that, in the event that there occurs a change in
25 AdvaMed standards that GUIDANT believes would require the adoption
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1 of practices that differ from or conflict with the practices prescribed by
2 this paragraph 9, GUIDANT shall notify the Multistate Executive
3 Committee (acting on behalf of the Attorneys General) of the new
4 standards, requirements or needs, and request that the Multistate Executive
5 Committee (on behalf of the Attorneys General) consent in writing to
6 modify this paragraph to the extent necessary to substitute such practices
7 for the practices prescribed by this paragraph 9, which consent shall not be
8 unreasonably withheld nor unreasonably delayed; and

- 9
- 10 ii. with respect to which GUIDANT shall display, in a clear and conspicuous
11 manner, a search engine on its website that permits a patient to search for
12 and identify safety advisories that have been issued since January 2005
13 with respect to devices implanted in such patient by inputting the model
14 and serial number of the device in the search engine; and
- 15 iii. Guidant shall make public safety advisories as soon as it can reasonably
16 do so after it notifies patients' physicians.

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

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

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26 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

1 returned to GUIDANT, permanently retired from use or otherwise permanently disposed
2 of.

3 13. Nothing in this Judgment shall require GUIDANT to:

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

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

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9 14. If, after the Effective Date of this Judgment, the United States, a State, or any foreign
10 government or governmental agency enacts or promulgates legislation, rules or regulations or
11 issues new regulatory requirements or FDA's Guidances for Industry with respect to matters
12 governed by this Judgment that conflict with any provision of this Judgment, GUIDANT shall
13 notify the Attorneys General (or the Attorney General of the affected State) of its intention to
14 comply with the newly enacted, promulgated or issued legislation, rule, regulation, requirements
15 or FDA Guidances for Industry, and the Attorneys General (or the Attorney General of the
16 affected State) shall consent to the modification of such provision to the extent necessary to
17 eliminate a conflict if GUIDANT cannot comply with both such legislation, rule, regulation,
18 requirements or FDA Guidances for Industry and the applicable provision of this Judgment.
19

20 **IV. SETTLEMENT FUND AND OTHER RELIEF**

21 15. GUIDANT shall extend the existing Warranty Supplement Program for patient costs
22 directly associated with the cost of repair or re-programming of the Covered ICDs to a date
23 ending no earlier than six months from the Effective Date.
24

25 16. One million dollars (\$1,000,000) of the payment referenced in paragraph 17 below that
26 GUIDANT makes to the States, shall be set aside by the States to cover, as much as possible,

1 direct patient costs that exceed the \$2,500.00 Warranty Supplement Program cap, for those
2 patients who request reimbursement for such payments and who are residents of Settling States.
3 Guidant shall make this one million dollar payment to the Attorney General of the State of
4 Oregon to be deposited in the Attorney General's Client Trust Account. The Oregon Attorney
5 General shall make payments from this amount as directed by the Multistate Executive
6 Committee. These funds shall be distributed within twelve (12) months of the Effective Date.
7 Any residue shall be equally distributed among the Settling States. Upon being provided with
8 appropriate waivers by the patients, and upon request by the Attorneys General, Guidant shall
9 provide the signatory Attorney General, within thirty (30) days of the request, records relating to
10 the application for refunds under the Warranty Supplement Program by patients residing in the
11 signatory Attorney General's Settling State, including payments made; partial payments made
12 and the reason why full payments were not made; and, denials of refunds and the reason why the
13 refunds were denied. Regardless of whether requested, Guidant shall give notice to the Attorney
14 General of the state in which the patient resides no later than sixty (60) days after it has issued a
15 final denial for payment of portions of a patient's claim for unreimbursed medical expenses that
16 exceed \$2,500 under the Unreimbursed Medical Expenses program related to the Warranty
17 Supplement Program available for the Covered ICDs. As designated and at the sole discretion of
18 the Multistate Executive Committee, the money set aside by this paragraph shall be divided and
19 paid to specific patients, who are residents of Settling States, either in full or on a pro rata basis,
20 for direct patient costs in excess of \$2,500.
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24 17. Within forty-five (45) days of the Effective Date of this Judgment, GUIDANT shall pay a
25 total amount of Sixteen Million Seven Hundred Fifty Thousand Dollars (\$16,750,000) to be
26 divided and paid by GUIDANT directly to each Settling State in an amount to be designated by

1 and in the sole discretion of the Multistate Executive Committee.² Said payment shall be used
2 by the States for attorneys' fees and other costs of investigation and litigation, or to be placed in,
3 or applied to, the consumer protection enforcement fund, consumer education, litigation or local
4 consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for
5 other uses permitted by state law, at the sole discretion of each signatory Attorney General.

6 18. Within one year of the Effective Date, GUIDANT shall provide the Multistate Executive
7 Committee with a report providing the number of individuals who submitted warranty
8 supplement claims under the Warranty Supplement Program; the number of individuals who
9 received any form of warranty consideration under the Warranty Supplement Program; and the
10 total warranty consideration paid under the Warranty Supplement Program. The Multistate
11 Executive Committee, the Attorneys General, and the Settling States shall maintain the
12 confidentiality of any report submitted pursuant to this paragraph 18, subject to the existing
13 confidentiality agreement between the parties.
14

15 **V. RELEASE**

16
17 19. By its execution of this Judgment, each Settling State releases Guidant and all of its past
18 and present parents, subsidiaries, affiliates, predecessors and successors (collectively, the
19 "Released Parties") from the following: all civil claims, causes of action, damages, restitution,
20 fines, costs, and penalties on behalf of the Settling States under the consumer protection statutes
21 cited in footnote 1 arising from the allegations that are the Subject Matter of this Judgment that
22 occurred at any time through and including the Effective Date of this Judgment.
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25 _____
26 ² With the exception of funds deposited into the Client Trust Account pursuant to paragraph 16
of this Judgment, Oregon's payment shall be deposited into the Consumer Protection and
Education Revolving Account established pursuant to ORS 180.095.

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

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

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

11 i. State or federal antitrust violations;

12 ii. Reporting practices, including “best price”, “average wholesale price” or
13 “wholesale acquisition cost;”

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

17 iv. State false claims violations.

18 c. Any liability under the Settling States' above-cited consumer protection laws
19 which any person or entity, including Released Parties, has or may have to individual
20 consumers or State program payers of said States, and which have not been specifically
21 enumerated as included here.
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23

24 VI. NO ADMISSION OF LIABILITY

25 21. This Judgment does not constitute an admission by GUIDANT for any purpose, of any
26 fact or of a violation of any state or federal law, rule, or regulation, nor does this constitute

1 evidence of any liability, fault, or wrongdoing. GUIDANT enters into this Judgment solely for
2 the purpose of resolving the allegations of the Attorneys General regarding GUIDANT ICDs.
3 GUIDANT does not admit any violation of ORS 646.605 *et seq* and does not admit any
4 wrongdoing that was or could have been alleged by any Attorney General before the date of the
5 Judgment under those laws set out in footnote 1.

6 22. This Judgment shall not be construed or used as a waiver or any limitation of any defense
7 otherwise available to GUIDANT. This Judgment is made without trial or adjudication of any
8 issue of fact or law or finding of liability of any kind. Nothing in this Judgment, including this
9 paragraph, shall be construed to limit or to restrict GUIDANT's right to use this Judgment to
10 assert and maintain the defenses of *res judicata*, collateral estoppel, payment, compromise and
11 settlement, accord and satisfaction, or any other legal or equitable defenses in any pending or
12 future legal or administrative action or proceeding.
13

14 **VII. COMPLIANCE REQUIREMENTS**

15 23. For the purpose of monitoring and investigating compliance with any provision of this
16 Judgment, GUIDANT shall create and maintain business records, policies, processes and
17 standard operating procedures to demonstrate compliance with the terms and provisions of this
18 Judgment. At a minimum, for a period of five (5) years, GUIDANT shall take reasonable steps
19 to:
20

- 21 a. Allow the Attorney General, or any of his or her representatives, reasonable
22 access to GUIDANT's business premises during normal business hours to inspect
23 relevant, non-Privileged and non-work-product records and documents that relate to
24 Guidant's compliance with this Judgment; or
25

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

6 c. Any information obtained by the Attorney General or his representative pursuant
7 to this paragraph shall be subject to the existing confidentiality agreement between the
8 parties.
9

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

12 a. Maintain copies of all data obtained by Guidant, in both raw and analyzed form,
13 including but not limited to pre-clinical, clinical, post-marketing or other scientific data
14 relating to an ICD, whether or not such data are generated by GUIDANT's own research
15 and development or monitoring, or by a third-party source; and
16

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

19 25. GUIDANT shall notify the Multistate Executive Committee at least five (5) business
20 days after any change in GUIDANT or Boston Scientific Corporation that may affect compliance
21 obligations arising out of this Judgment, including any dissolution of GUIDANT or Boston
22 Scientific Corporation, or any acquisition, merger, or consolidation of GUIDANT or Boston
23 Scientific Corporation.
24

25 26. Nothing in this Judgment shall be construed as:
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1 a. relieving GUIDANT of its obligation to comply with all state laws, regulations or
2 rules, or granting permission to engage in any acts or practices prohibited by such law,
3 regulation or rule; or

4 b. limiting or expanding in any way any right the State may otherwise have to obtain
5 information, documents or testimony from GUIDANT pursuant to any state law,
6 regulation or rule, or any right GUIDANT may otherwise have to oppose any subpoena,
7 civil investigative demand, compulsory process, motion, or other procedure issued,
8 served, filed, or otherwise employed by the State pursuant to any such state law,
9 regulation or rule.
10

11 27. In the event that the Multistate Executive Committee, any Attorney General, or any
12 Settling State is served with a freedom of information act or similar request, or with any
13 subpoena or other legal process, requesting or requiring it to provide or produce any report or
14 information provided by GUIDANT pursuant to paragraph 18 or any information obtained
15 pursuant to paragraph 23 of this Judgment, the Multistate Executive Committee, such Attorney
16 General, and/or such Settling State (as the case may be) shall inform GUIDANT within ten (10)
17 calendar days of receipt of such request, subpoena, or legal process and no less than ten (10)
18 business days before any deadline for responding to such request, subpoena, or legal process, and
19 GUIDANT shall have the right and responsibility in its sole discretion to challenge such request,
20 subpoena or legal process.
21

22 **VIII. REPRESENTATIONS AND WARRANTIES**

23
24 28. GUIDANT acknowledges that it is the proper party to this Judgment. GUIDANT
25 warrants and represents that the individual signing this Judgment on behalf of Guidant is doing
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1 so in his or her official capacity and is fully authorized by GUIDANT to enter into this Judgment
2 and to legally bind GUIDANT to all of the terms and conditions of this Judgment.

3 29. The Attorneys General signatory warrants and represents that he or she is signing this
4 Judgment in his or her official capacity, and that he or she is fully authorized by his or her state
5 to enter into this Judgment, including but not limited to the authority to grant the release
6 contained in Paragraphs 19 and 20 of this Judgment, and to legally bind the state to all of the
7 terms and conditions of this Judgment.
8

9 **IX. ORDER DISTRIBUTION**

10 30. Within sixty (60) days of the Effective Date of this Judgment and for a period of no less
11 than seven (7) years from the Effective Date, GUIDANT shall cause all of its vice presidents or
12 higher corporate officers (regardless of contact with patients, physicians, hospitals, or research
13 institutions), to review a copy of this Judgment. GUIDANT shall also provide a copy of this
14 Judgment to all of its new vice presidents or higher corporate officers, within thirty (30) days of
15 hiring such person. GUIDANT shall obtain from each person who has received this Judgment an
16 electronic certification acknowledging that he/she reviewed this Judgment. GUIDANT shall
17 maintain such acknowledgement for a minimum of three (3) years from the date each is provided
18 to GUIDANT and shall make them available for inspection and copying upon request of any
19 representative of the Settling States' Attorneys General.
20

21 **X. DISPUTES REGARDING COMPLIANCE**

22 31. For the purposes of resolving disputes with respect to compliance with this Judgment,
23 should the Attorney General have legally sufficient cause (which shall include, at a minimum, a
24 reasonable basis to believe that Guidant has violated a provision of this Judgment), then the
25 Attorney General shall notify Guidant in writing of the specific objection, identify with
26

1 particularity the provisions of this Judgment and/or the State Consumer Protection Laws that the
2 practice appears to violate, and give Guidant thirty (30) business days to respond to the
3 notification; provided, however, that the Attorney General may take any action upon notice to
4 Guidant where the Attorney General concludes that, because of the specific practice, a threat to
5 the health or safety of the public requires immediate action.

6 32. Upon receipt of written notice and within the thirty (30) business-day period, Guidant
7 shall provide a good faith written response to the Attorney General's objection. The response
8 shall include an affidavit containing either:
9

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

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

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

15 ii. A statement that the alleged breach cannot be reasonably cured within
16 thirty (30) business days from receipt of the notice, but (1) Guidant has begun to
17 take corrective action to cure the alleged breach; (2) Guidant is pursuing such
18 corrective action with reasonable and due diligence; and (3) Guidant has provided
19 the Attorney General with a detailed and reasonable time table for curing the
20 alleged breach.
21

22 33. Nothing herein shall prevent the Attorney General from agreeing in writing to provide
23 Guidant with additional time beyond the thirty (30) business-day period to respond to the notice.
24

25 34. Nothing herein shall be construed to exonerate any failure to comply with any provision
26 of this Judgment after the date of entry or to compromise the authority of the Signatory Attorney

1 General to initiate a proceeding for failure to comply. Further, nothing in this subsection shall be
2 construed to limit the authority of the Signatory Attorney General to protect the interests of the
3 State.

4 35. The Signatory Attorney General represents that he or she will seek enforcement of the
5 provisions of this Judgment with due regard for fairness and, in so doing, shall take into account
6 efforts that Guidant has taken to cure any claimed violation of this Judgment.
7

8 **XI. ENFORCEMENT**

9 36. Any party to this Judgment may apply to a court of competent jurisdiction at any time for
10 such further orders and directions as are necessary or appropriate for carrying out this Judgment,
11 including the modification of the injunctive provisions, the enforcement of compliance, and the
12 punishment of violations as permitted by law.

13 **XII. NOTICES**

14 37. Any notices provided pursuant to the requirements of this Judgment shall be deemed given
15 five (5) business days after mailing or one (1) business day after facsimile or e-mail
16 transmission. All such notices shall be in writing and shall be addressed as follows:
17

18 To GUIDANT:

19 Jean Holloway, Esq.
20 Vice President, Legal
21 Boston Scientific Corporation
22 Cardiac Rhythm Management
23 4100 Hamline Ave North
24 St. Paul, Minnesota 55112-5798
25 Tel: 651-582-7501
26 Fax: 651-582-7400

27 with a copy to:

28 Timothy Pratt, Esq.
29 Shook, Hardy & Bacon L.L.P.
30 2555 Grand Boulevard

1 Kansas City, Missouri 64108-2613

2 Tel: 816-474-6550

3 Fax: 816-421-5547

4 To the State of Oregon:

5 David Hart, Esq.

6 Assistant Attorney General

7 1162 Court Street NE

8 Salem, OR 97301-4096

9 Tel: (503) 947-4333

10 Fax: (503) 378-5017

11 To Multistate Executive Committee or to the Oregon Attorney General:

12 David Hart, Esq.

13 Assistant Attorney General

14 1162 Court Street NE

15 Salem, OR 97301-4096

16 Tel: (503) 947-4333

17 Fax: (503) 378-5017

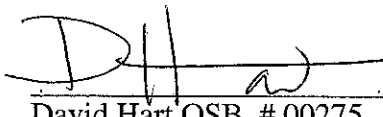
18 **IT IS SO ADJUDGED AND ORDERED:**

19 DATED this 30 day of August, 2007.

20 
21 _____
22 CIRCUIT COURT JUDGE
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FOR THE STATE OREGON
HARDY MYERS

 8/30/07

David Hart OSB # 00275
Assistant Attorney General
Oregon Department of Justice
Of Attorneys for Plaintiff
Financial Fraud/Consumer Protection Section
1162 court Street NE
Salem, OR 97301-4096
Phone: (503) 947-4333
Fax: (503) 378-5017
Email: david.hart@doj.state.or.us

FOR GUIDANT:

LANE POWELL PC

By: 

Steven B. Ungar, OSB No. 960029
601 SW Second Avenue, Suite 2100
Portland, Oregon 97204-3158
Tel: (503) 778-2100
Fax: (503) 778-2200
ungars@lanepowell.com

Date: 8-17-07

FOR GUIDANT:

By: William F. McConnell, Jr.
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

[Faint, illegible text, possibly a stamp or bleed-through]