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14 **ARIZONA SUPERIOR COURT**

15 **COUNTY OF PIMA**

17 State of Arizona, ex rel. Terry Goddard,
Attorney General,

18 Plaintiff,

19 vs.

20 Guidant Corporation, Cardiac
21 Pacemakers, Inc., and Guidant Sales
22 Corporation,

23 Defendants.

No. _____

ORDER FOR CONSENT JUDGMENT

24
25 Based on the parties' Joint Motion to Enter Consent Judgment and good cause
26 appearing,

27 THE COURT HEREBY FINDS AND ORDERS:

28 1. The State of Arizona filed a complaint alleging violations of A.R.S. § 44-1521 *et*

State v. Guidant Corporation

1 seq., the Consumer Fraud Act against defendant Guidant Corporation, Guidant Sales
2 Corporation, and Cardiac Pacemakers, Inc. (hereinafter referred to as "Guidant").

3 2. This Order incorporates the parties' Joint Motion to Enter Consent Judgment in
4 *State v. Guidant Corporation*.

5 **STIPULATED FINAL JUDGMENT AND PERMANENT INJUNCTION**

6 **I. FINDINGS**

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

9 2. The terms of this Final Judgment ("Judgment") shall be governed by the laws of
10 the State of Arizona.

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

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

27 5. This Judgment is applicable to GUIDANT and to GUIDANT's agents, employees,
28 representatives, assignees, and successors in interest who have actual or constructive

1 notice of its provisions (hereinafter collectively “Enjoined Persons”).

2 **II. DEFINITIONS**

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

4 A. “AdvaMed” means the Advanced Medical Technology Association
5 (AdvaMed).

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

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

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

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

20 F. “FDA” means the U.S. Food and Drug Administration.

21 G. “FDA’s Guidances for Industry” means documents published by the FDA
22 that represent the FDA’s current recommendations on a topic.

23 H. “FDCA” means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §
24 301 et seq., as the same may be amended.

25 I. Unless otherwise specified, “GUIDANT” means Guidant Corporation,
26 Cardiac Pacemakers, Inc., and Guidant Sales Corporation, and their successors
27 and assigns.

28 J. Unless otherwise specified, “Implantable Cardioverter Defibrillator” or

1 "ICD" means a device implanted in the chest that was approved by the FDA at
2 any time from and after January 2000 that monitors for and, if necessary
3 corrects, certain episodes of an abnormal heart rhythm.

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

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

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

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

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

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

24 _____
25 ¹ ALASKA Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 et seq; ARIZONA -
26 Consumer Fraud Act, Ariz. Rev. Stat. §44-1521, et. seq.; ARKANSAS - Deceptive Trade Practices Act,
27 Ark. Code Ann. § 4-88-101 et seq.; CALIFORNIA Business and Professions Code § 17200 et seq. 17500
28 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

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,
4 above.

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

10 **III. COMPLIANCE PROVISIONS**

11 **PERMANENT INJUNCTION**

12 7. For a period of no less than five (5) years from the Effective Date, GUIDANT
13 shall establish an Independent Patient Safety Advisory Board, beginning within one
14 hundred twenty (120) days following the Effective Date, to evaluate data concerning
15 ICD performance and risk assessment data. The Patient Safety Advisory Board shall
16 include independent experts whose expertise includes cardiac electrophysiology,
17

18 Deceptive Business Practices Act, 815 ILCS § 505/1 et seq. (2002); KANSAS - Kansas Consumer
19 Protection Act: K.S.A. 50-623 et seq; KENTUCKY - Consumer Protection Statute, KRS 367.170 et seq;
20 LOUISIANA - Unfair Trade Practices and Consumer Protection Law, LSA-R.S. 51:1401 et seq.; MAINE -
21 Unfair Trade Practices Act, 5 M.R.S.A. section 205-A et. seq.; MARYLAND - Consumer Protection Act,
22 Maryland Commercial Law Code Annotated § 13-101 et seq.; MASSACHUSETTS - Consumer Protection
23 Act, M.G.L. c. 93A et seq.; MICHIGAN - Michigan Consumer Protection Act, MCL 445.901 et seq. ;
24 MISSISSIPPI -Miss. Code Ann. § 75-24-1 et seq., (1972) as amended ; MISSOURI -MISSOURI -
25 Merchandising Practices Act, Mo. Rev. Stat. Sections 407.020 and 407.100; MONTANA - Mont. Code
26 Ann. § 30-14-101 et seq.; NEVADA - Deceptive Trade Practices Act, Nevada Revised Statutes 598.0903
27 et seq.; NEW JERSEY -New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq ; NEW MEXICO - Unfair
28 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.

1 engineering, statistics, risk management, and bioethics. At least one member of the
2 board will represent the views of patients. The board's function shall be linked to
3 GUIDANT by the Patient Safety Officer as set forth in paragraph 8, below. GUIDANT
4 may reasonably compensate members of the board at a rate that is normal and
5 customary in the market for persons performing similar services.

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

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

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

28 i. whether the confirmed malfunctions occurred in a manner that did or

- 1 did not compromise pacing or defibrillation therapy;
- 2 ii. failure pattern (root cause);
- 3 iii. whether modifications have been made to address the failure pattern;
- 4 and
- 5 iv. whether safety advisories have been issued for such product
- 6 families.
- 7 b. United States data on survival probability estimates:
- 8 i. for ICD product families that have a minimum of 10,000 implant
- 9 months and an active population of 200 devices remaining in the
- 10 United States; or
- 11 ii. in the event that AdvaMed modifies the Applicable Standard, for
- 12 ICD product families having a minimum number of implant months
- 13 and an active population of devices that comply with such modified
- 14 Applicable Standard;
- 15 c. Current information related to any safety advisory classified by the FDA as
- 16 a Class I or Class II recall:
- 17 i. (A) for which there is an estimated active United States
- 18 population of at least 200 devices; or
- 19 (B) in the event that AdvaMed modifies the Applicable Standard,
- 20 for which there is an estimated active United States population
- 21 equal to or greater than the population specified in such modified
- 22 Applicable Standard; provided that, in the event that there occurs a
- 23 change in AdvaMed standards that GUIDANT believes would
- 24 require the adoption of practices that differ from or conflict with the
- 25 practices prescribed by this paragraph 9, GUIDANT shall notify the
- 26 Multistate Executive Committee (acting on behalf of the Attorneys
- 27 General) of the new standards, requirements or needs, and request
- 28 that the Multistate Executive Committee (on behalf of the Attorneys

- 1 General) consent in writing to modify this paragraph to the extent
2 necessary to substitute such practices for the practices prescribed
3 by this paragraph 9, which consent shall not be unreasonably
4 withheld nor unreasonably delayed; and
- 5 ii. with respect to which GUIDANT shall display, in a clear and
6 conspicuous manner, a search engine on its website that permits a
7 patient to search for and identify safety advisories that have been
8 issued since January 2005 with respect to devices implanted in
9 such patient by inputting the model and serial number of the device
10 in the search engine; and
- 11 iii. Guidant shall make public safety advisories as soon as it can
12 reasonably do so after it notifies patients' physicians.
- 13 d. GUIDANT shall provide links on its website to its Medical Device
14 Reporting ("MDR") reports maintained by the FDA that pertain to ICDs.
- 15 e. Notwithstanding anything to the contrary in this paragraph 9, if GUIDANT
16 makes a modification to address a failure pattern resulting in loss of therapy,
17 GUIDANT shall post on its website the existence of such modification in the next
18 quarterly product performance report, but in no event later than thirty (30) days
19 after such modification is implemented.
- 20 10. GUIDANT shall not be required to make the disclosures described in paragraph
21 9:
- 22 a. with respect to any New ICD until the first annual anniversary of the first
23 commercial sale of such New ICD by GUIDANT, to permit GUIDANT sufficient
24 time to collect meaningful data concerning such New ICD; and
- 25 b. at all with respect to any Discontinued ICDs; and
- 26 c. with respect to any country or other jurisdiction whose laws prohibit
27 GUIDANT from disclosing such information with respect to citizens or residents
28 of, or medical devices sold or located in, that country or jurisdiction; and

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

2 11. For a period of no less than seven (7) years from the Effective Date, GUIDANT
3 shall solicit the return of out-of-service ICDs to assist in gathering information provided
4 for in paragraph 9, above, to the extent permitted by (a) the law of the jurisdiction in
5 which the patient resides, is domiciled and/or can be found; or (b) the law of jurisdiction
6 where the device return is solicited.

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

- 11 a. the device's lot number, batch number, model number, or serial number,
12 or other identifier necessary to provide for effective tracking of the device;
- 13 b. the date the device was shipped by GUIDANT;
- 14 c. the date the device was implanted in the patient; and,
- 15 d. if applicable and to the extent available or known to GUIDANT, the date
16 the device was explanted, or the date of the patient's death, or the date the
17 device was returned to GUIDANT, permanently retired from use or otherwise
18 permanently disposed of.

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

- 20 a. take an action that is prohibited by the FDCA or any applicable federal law
21 or regulation, or by the FDA; or
- 22 b. fail to take an action that is required by the FDCA or any applicable federal
23 law or regulation, or by the FDA.

24 14. If, after the Effective Date of this Judgment, the United States, a State, or any
25 foreign government or governmental agency enacts or promulgates legislation, rules or
26 regulations or issues new regulatory requirements or FDA's Guidances for Industry with
27 respect to matters governed by this Judgment that conflict with any provision of this
28 Judgment, GUIDANT shall notify the Attorneys General (or the Attorney General of the

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

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

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

11 16. One million dollars (\$1,000,000) of the payment referenced in paragraph 17
12 below that GUIDANT makes to the States, shall be set aside by the States to cover, as
13 much as possible, direct patient costs that exceed the \$2,500.00 Warranty Supplement
14 Program cap, for those patients who request reimbursement for such payments and
15 who are residents of Settling States. Guidant shall make this one million dollar payment
16 to the Attorney General of the State of Oregon to be deposited in the Attorney General's
17 Client Trust Account. The Oregon Attorney General shall make payments from this
18 amount as directed by the Multistate Executive Committee. These funds shall be
19 distributed within twelve (12) months of the Effective Date. Any residue shall be equally
20 distributed among the Settling States. Upon being provided with appropriate waivers by
21 the patients, and upon request by the Attorneys General, Guidant shall provide the
22 signatory Attorney General, within thirty (30) days of the request, records relating to the
23 application for refunds under the Warranty Supplement Program by patients residing in
24 the signatory Attorney General's Settling State, including payments made; partial
25 payments made and the reason why full payments were not made; and, denials of
26 refunds and the reason why the refunds were denied. Regardless of whether
27 requested, Guidant shall give notice to the Attorney General of the state in which the
28 patient resides no later than sixty (60) days after it has issued a final denial for payment

1 of portions of a patient's claim for unreimbursed medical expenses that exceed \$2,500
2 under the Unreimbursed Medical Expenses program related to the Warranty
3 Supplement Program available for the Covered ICDs. As designated and at the sole
4 discretion of the Multistate Executive Committee, the money set aside by this paragraph
5 shall be divided and paid to specific patients, who are residents of Settling States, either
6 in full or on a pro rata basis, for direct patient costs in excess of \$2,500.

7 17. Within forty-five (45) days of the Effective Date of this Judgment, GUIDANT shall
8 pay a total amount of Sixteen Million Seven Hundred Fifty Thousand Dollars
9 (\$16,750,000) to be divided and paid by GUIDANT directly to each Settling State in an
10 amount to be designated by and in the sole discretion of the Multistate Executive
11 Committee. Said payment shall be used by the Arizona Attorney General for consumer
12 fraud education and investigative and enforcement operations of the consumer
13 protection division pursuant to A.R.S. Section 44-1531.01 and for costs and attorney's
14 fees pursuant to A.R.S. Section 44-1534.

15 18. Within one year of the Effective Date, GUIDANT shall provide the Multistate
16 Executive Committee with a report providing the number of individuals who submitted
17 warranty supplement claims under the Warranty Supplement Program; the number of
18 individuals who received any form of warranty consideration under the Warranty
19 Supplement Program; and the total warranty consideration paid under the Warranty
20 Supplement Program. The Multistate Executive Committee, the Attorneys General, and
21 the Settling States shall maintain the confidentiality of any report submitted pursuant to
22 this paragraph 18, subject to the existing confidentiality agreement between the parties.

23 **V. RELEASE**

24 19. By its execution of this Judgment, each Settling State releases Guidant and all of
25 its past and present parents, subsidiaries, affiliates, predecessors and successors
26 (collectively, the "Released Parties") from the following: all civil claims, causes of
27 action, damages, restitution, fines, costs, and penalties on behalf of the Settling States
28 under the consumer protection statutes cited in footnote 1 arising from the allegations

1 that are the Subject Matter of this Judgment that occurred at any time through and
2 including the Effective Date of this Judgment.

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

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

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

12 i. State or federal antitrust violations;

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

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

18 iv. State false claims violations.

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

23 **VI. NO ADMISSION OF LIABILITY**

24 21. This Judgment does not constitute an admission by GUIDANT for any purpose,
25 of any fact or of a violation of any state or federal law, rule, or regulation, nor does this
26 constitute evidence of any liability, fault, or wrongdoing. GUIDANT enters into this
27 Judgment solely for the purpose of resolving the allegations of the Attorneys General
28 regarding GUIDANT ICDs. GUIDANT does not admit any violation of the State of

1 Arizona's Consumer Fraud Act and does not admit any wrongdoing that was or could
2 have been alleged by any Attorney General before the date of the Judgment under
3 those laws set out in footnote 1.

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

12 VII. COMPLIANCE REQUIREMENTS

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

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

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

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

1 agreement between the parties.

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

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

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

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

17 26. Nothing in this Judgment shall be construed as:

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

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

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

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

10 **VIII. REPRESENTATIONS AND WARRANTIES**

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

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

21 **IX. ORDER DISTRIBUTION**

22 30. Within sixty (60) days of the Effective Date of this Judgment and for a period of
23 no less than seven (7) years from the Effective Date, GUIDANT shall cause all of its
24 vice presidents or higher corporate officers (regardless of contact with patients,
25 physicians, hospitals, or research institutions), to review a copy of this Judgment.
26 GUIDANT shall also provide a copy of this Judgment to all of its new vice presidents or
27 higher corporate officers, within thirty (30) days of hiring such person. GUIDANT shall
28 obtain from each person who has received this Judgment an electronic certification

1 acknowledging that he/she reviewed this Judgment. GUIDANT shall maintain such
2 acknowledgement for a minimum of three (3) years from the date each is provided to
3 GUIDANT and shall make them available for inspection and copying upon request of
4 any representative of the Settling States' Attorneys General.

5 **X. DISPUTES REGARDING COMPLIANCE**

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

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

- 19 a. A statement explaining why Guidant believes it is in compliance with the
20 Judgment; or
21 b. A detailed explanation of how the alleged violation[s] occurred; and
22 i. A statement that the alleged breach has been cured and how it has
23 been cured; or
24 ii. A statement that the alleged breach cannot be reasonably cured
25 within thirty (30) business days from receipt of the notice, but (1) Guidant
26 has begun to take corrective action to cure the alleged breach; (2) Guidant
27 is pursuing such corrective action with reasonable and due diligence; and
28 (3) Guidant has provided the Attorney General with a detailed and

1 reasonable time table for curing the alleged breach.

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

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

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

14 **XI. ENFORCEMENT**

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

19 **XII. NOTICES**

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

24
25
26
27
28

State v. Guidant Corporation

1 TO GUIDANT:

2 Jean Holloway, Esq.
3 Vice President, Legal
4 Boston Scientific Corporation
5 Cardiac Rhythm Management
6 4100 Hamline Ave North
7 St. Paul, Minnesota 55112-5798
8 Tel: 651-582-7501
9 Fax: 561-582-7400

10 with a copy to:

11 Timothy Pratt, Esq.
12 Shook, Hardy & Bacon L.L.P.
13 2555 Grand Boulevard
14 Kansas City, Missouri 64108-2613
15 Tel: 816-474-6550
16 Fax: 816-421-5547

17 TO THE STATE OF ARIZONA:

18 Noreen R. Matts
19 Assistant Attorney General, Unit Chief Counsel
20 Consumer Protection and Advocacy
21 Arizona Attorney General's Office
22 400 W. Congress, S-Bldg., Third Floor
23 Tucson, AZ 85701
24 Tel: (520) 628-6577
25 Fax: (520) 628-6532

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

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

Dated this _____ day of August, 2007.

JUDGE OF SUPERIOR COURT

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