

# **EXHIBIT B**

October 9, 2006

VIA ELECTRONIC MAIL

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**Re: In re: Guidant Corp. Implantable Defibrillators Products Liability Litigation,  
MDL 1708: Confidentiality Objections**

Dear Counsel:

I have received your September 29, 2006 letter attaching the Affidavit of Ronald S. Goldser ("Plaintiffs' affidavit") and containing your objection to "the confidential designation of all documents identified on the attached affidavit." After a complete review of the documents listed in Plaintiffs' affidavit, Guidant responds to your objection as follows:

**A. Deposition Designations**

Plaintiffs request the dedesignation of certain pages from depositions of Ren Russie, Keith Johnson, Randy Nuernberg, Chris Harrold, Robert Sheridan, and Brian Novak. First, Guidant notes that any request for dedesignation of confidentiality designations as to the depositions of Mr. Russie and Mr. Sheridan are premature as Guidant has not yet made confidentiality designations for the transcripts cited in Plaintiffs' affidavit at numbers 95 and 99.

Second, all confidentiality designations previously made by Guidant in deposition transcripts were made by page and line number. Plaintiffs have not specified the lines they request to be dedesignated. Until Plaintiffs provide the specific line numbers, Guidant cannot respond to Plaintiffs' request for dedesignations as to confidentiality.

**B. Plaintiffs' expert reports**

Plaintiffs have objected to the confidentiality designations of two of Plaintiffs' experts' reports, those for Suzanne Parisian and Randolph Armstrong. To the extent that these reports discuss, cite to, or rely upon in any way confidential Guidant documents or information, the documents and information, and any discussion thereof or quotes therefrom, must remain confidential and under seal.

Geneva  
Houston  
Kansas City  
London  
Miami  
Orange County  
Overland Park  
San Francisco  
Tampa  
Washington, D.C.

### **C. Documents not produced by Guidant**

Ten documents objected to by Plaintiffs do not contain Guidant bates-stamps and do not appear to have been produced by Guidant. In fact, several are publicly available documents, which Plaintiffs apparently obtained from outside sources. Because these documents were not produced by Guidant in this action, Guidant has made no designation as to their confidential status in the MDL litigation. These documents clearly should not have been part of Plaintiffs' confidentiality objection.

As to document number 9 on Plaintiffs' affidavit, this document was produced and designated as confidential by Accellent, Inc. Any objection as to the confidentiality designation of this document should be addressed to Accellent, Inc., not Guidant.

1. The Future of Drug Safety: Promoting and Protecting the Health of the Public. Written by the Committee on the Assessment of the US Drug Safety System Board on Population Health and Public Health Practice for the Institute of Medicine of the National Academies. Published by The National Academies Press, Washington, D.C. (September 2006);
2. DuPont POLICY Regarding Medical Applications of DuPont Materials, September 30, 2002; Appendix B: DuPont Policy Regarding Medical Applications of DuPont Materials (initial policy);
3. *Perry v. Novartis*, No. 2:05-cv-5350 (E.D. Pa.) (FDA Amicus Brief);
4. Endovascular Plea Agreement, June 12, 2003;
5. Document described as "Endovascular Corporate Integrity Agreement, June 12, 2003" (actually a DOJ press release);
6. Guidant Form 10-Q;
7. Contak Renewal Health Hazard Evaluation (FDA GUIDANT 000003338);
8. Prizm 2 Health Hazard Evaluation (FDA GUIDANT 000003341 - 000003343);
9. Polyimide Enamel Equivalency Summary (1/USDOJ/ACC/8/00109);

10. U.S. GAO, AVIATION SAFETY FAA AND DOD RESPONSE TO SIMILAR SAFETY CONCERNS, GAO-02-77 (WASHINGTON, D.C.: JAN. 22, 2002);

**D. Documents which were produced by Guidant, but which were not designated confidential**

Eight of documents listed in Plaintiffs' affidavit were produced by Guidant but Guidant has not designated them as confidential in the MDL litigation. Because these documents were produced by Guidant without the confidential designation, there is no further action required with respect to these specific documents. Again, Plaintiffs' objection to the alleged confidential designation of these documents is nonsensical.

15. 2000 Prizm 2 FDA Approval Letter (CPI 2 00000001 – 00000002)
31. December 2005 FDA Warning Letter (CPI 69 00000001 – 00000004)
32. June 2005 Recall Classification Letter (CPI 77 00000012)
34. May 2005 Prizm 2 Powerpoint Presentation (CPI 84 00000982 – 00001008)
35. May 2005 New York Times Article (CPI 84 00004421 – 00004425)
61. May 2002 Contak CD FDA Approval Letter (CPI 95 00000001 – 00000009)
62. July 1997 Ventak AV FDA Approval Letter (CPI 95 00000108 – 00000116)
82. Independent Panel Report (CPI 130 – 00000001 – 000000135)

**E. Documents which Guidant will agree to dedesignate as confidential**

Guidant has reviewed the following documents and Guidant agrees to dedesignate the following documents as confidential. Guidant will reproduce these documents without the confidentiality designation with one exception. Document number 81 on Plaintiffs' affidavit was produced as part of a larger document for which Guidant is not willing to dedesignate as confidential. Therefore only the pages cited by Plaintiffs in the affidavit will be dedesignated.

13. Prizm 2 Limited Warranty (CPI 1 00001968 – 00001973)
14. 2002 Prizm 2 FDA Approval Letter (CPI 1 00003727 – 00003734)
23. 2002 Contak Renewal FDA Approval Letter (CPI 22 000014578 – 000014585)
57. June 17, 2005 Prizm 2 Dear Doctor Letter (CPI 93 00046544 – 00046546)
58. June 17, 2005 Contak Renewal Dear Doctor Letter (CPI 93 00047988 – 00047990)
69. May 23, 2005 Prizm 2 Dear Doctor Letter (CPI 101 00021484)
74. Prizm 2 Limited Warranty Letter (CPI 118 00000089 – 00000090)
81. Conference Record of the 1992 IEEE International Symposium on Electrical Insulation (only CPI 121 00001685 – 00001689)
94. Kapton General Specifications (CPI 187 00010296 – 00010303)

**F. Documents for which Guidant maintains its confidential designations**

As to the remaining documents listed on Plaintiffs' affidavit, Guidant maintains its confidential designation of these documents. These documents are subject to confidentiality protection under the court's protective order and existing law, as they contain trade secret or proprietary information that, if made public, will cause substantial and irreparable harm to Guidant.

16. 2000 Prizm 2 PMA Supplement (CPI 2 00000003 – 00000100)
17. Prizm 2 Header Assembly Diagram (CPI 2 00000103 – 00000104)
18. 2000 Prizm 2 Reliability Prediction Report (CPI 2 00001361 – 00001375)
19. 2000 Prizm 2 Biocompatibility Assessment (CPI 2 00001597 – 00001609)
20. 2005 Contak Renewal 3 PMA Supplement (CPI 2 00016597 – 00016622)

21. 2005 Real Time Review Request for PEEK Tubing (CPI 4 00031192 – 00031196)
22. 2002 Contak Renewal PMA Supplement (CPI 22 00011330 – 00011448)
24. Field Discrepancy Notification Report – FDN02026 (CPI 35 0000003, incorrectly cited in Plaintiffs' affidavit as CPI 35 00000001)
25. Field Discrepancy Notification Report – FDN02051 (CPI 35 0000002)
26. Field Discrepancy Notification Report – FDN02065 (CPI 35 0000001, incorrectly cited in Plaintiffs' affidavit as CPI 35 0000003)
27. June 2002 Prizm 2 Risk Assessment Form (CPI 35 0000004 – 0000006)
28. Event Summaries (CPI 35 0000135 – 0000140, incorrectly cited in Plaintiffs' affidavit as CPI 36 00000159 – 000000161)
29. Renewal 1-2 Trend Report (CPI 36 00000203 – 00000206)
30. Prizm 2 Manufacturing Instructions (CPI 63 00557886 – 00557912)
33. Prizm 2 Feedthru Diagram (CPI 83 00070269)
36. August 31, 2005 FDA Inspection Notes (CPI 87 00002769 – 00002781)
37. August 22, 2005 FDA Inspection Notes (CPI 87 00009314 – 00009320)
38. August 23, 2005 FDA Inspection Notes (CPI 87 00010061 – 00010063)
39. August 24, 2005 FDA Inspection Notes (CPI 87 00010246 – 00010251)

40. August 25, 2005 FDA Inspection Notes (CPI 87 00011386 – 00011392)
41. August 30, 2005 FDA Inspection Notes (CPI 87 00012436 – 00012437)
42. August 29, 2005 FDA Inspection Notes (CPI 87 00021256 – 00021258)
43. Field Discrepancy Notification FDN 5373 (CPI 87 00027883 – 00027885)
44. PEC Informational Update – Powerpoint (CPI 87 00027935 – 00027971)
45. Engineering Change Order No. 41940 (CPI 87 00027985 – 00028005)
46. Renewal Stop Order (CPI 88 0039817 – 00040035)
47. 1996 Mini III Requirements Analysis (CPI 88 00081462 – 00081476)
48. 1995 Mini III Requirements Analysis (CPI 88 00070884 – 00070901)
49. Engineering Change Order 40773 (CPI 90 00041300 – 00041321)
50. June 2005 FDA Meeting Notes (CPI 92 00006762 – 00006766)
51. May 2005 FDA Meeting Notes (CPI 92 00008712 – 00008715)
52. May 2005 FDA Meeting Notes (CPI 92 00009132 – 00009134)
53. Guidant's Response to FDA's Prizm 2 Questions (CPI 92 00011296 – 00011302)
54. May 2005 Powerpoint to FDA (CPI 92 00021144 – 00021150)
55. Tachy Field Performance Meeting Minutes (CPI 93 00029649 – 00029663)
56. Mini I Trend Documentation (CPI 93 00036860 – 00036917)

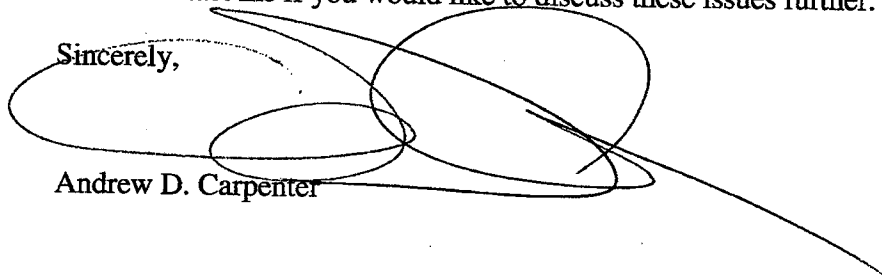
59. Prizm 2 Mechanical Requirements (CPI 94 00135885 – 00135886)
60. Kapton Change Order (CPI 94 00138755 – 00138757)
63. Ventak AV PMA (CPI 100 0000001 – 000002682)
64. December 1991 Ventak PRx PMA Letter (CPI 100 00012709 – 00012712)
65. Ventak PRx Second Amendment (CPI 100 00019001)
66. Ventak PRx IDE Amendment (CPI 100 00020954 – 00020955)
67. Component Evaluation Test Report: Polyimide Tubing (CPI 100 00021035 – 00021050)
68. March 1992 Ventak PRx IDE Supplement (CPI 100 00056092 – 00056103)
70. PRO History of Prizm 2 (CPI 101 00062401 – 00062407)
71. Event Summaries (CPI 103 00000043 – 00000051)
72. Guidant Response to FDA Prizm 2 Question No. 1 (Plaintiffs cited CPI 109 00000310 – 00000311 in the affidavit, but attached CPI 109 0000309 – 0000310. Guidant maintains the confidentiality designation of all four pages.)
73. January 1999 Mini Trend Report (CPI 113 00015862 - 00015870)
75. Standard Operating Procedure: Risk Assessment (CPI 119 00012731 – 00012739)
76. Department Operating Procedure: Trending of Field Performance Data (CPI 119 00013760 – 00013764)
77. Department Operating Procedure: Field Discrepancy Notification (CPI 119 00016772 – 00016786)
78. Department Operating Procedure: Trending of Field Performance Data (CPI 119 00062515 – 00062523)



79. Department Operating Procedure: Field Discrepancy Notification (CPI 119 00069763 – 00069775)
80. Standard Operating Procedure: Risk Assessment (CPI 119 00082379 – 00082390)
83. Field Discrepancy Notification No. 6309 (CPI 36 0000159 – 0000161, incorrectly cited in Plaintiffs' affidavit as CPI 135 0000135 – 0000140)
84. Prizm 2 Trend Report Revision A (CPI 168 00003089 – 00003091)
85. Prizm 2 Trend Report Revision C (CPI 168 0003095 – 00003097)
86. PPC Decision Making meeting Powerpoint (CPI 168 00003316 – 00003320)
87. Prizm 2 Trend Report Revision D (CPI 168 00004080 – 00004085)
88. Polyimide Bend Test Results (CPI 179 00001204 – 00001206)
89. June 2002 Prizm 2 Risk Assessment (CPI 179 00002570 – 00002571)
90. Exporters Certification Statement (CPI 183 00008680 – 0008681, incorrectly cited in Plaintiffs' affidavit as CPI 183 00021894)
91. Prizm 2 Device Inventory Numbers (CPI 183 000021894, incorrectly cited in Plaintiffs' affidavit as CPI 183 00050762 – 00050767)
92. Guidant's Responses to FDA's Prizm 2 Questions (183 00050762 – 0050757, incorrectly cited in Plaintiffs' affidavit as CPI 183 0008680 – 0008681)
93. June 2005 FDA Prizm 2 Summary (CPI 187 00000868 – 00000873)

Please contact me if you would like to discuss these issues further.

Sincerely,

A large, stylized handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke extending to the right.

Andrew D. Carpenter