GUIDANT

August 17, 2001

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Re: Annual Report for PMA P960040 - VENTAK® AV™ and VENTAK PRIZM DR/VR Automatic Implantable Cardioverter Defibrillator

Enclosed is the annual report for the VENTAK AV family of Automatic Implantable Cardioverter Defibrillators (AICD™) as required in the Conditions of Approval Letter for PMA P960040 (dated July 18, 1997) and subsequent supplements to the PMA. The information in this report covers the period between June 1, 2000 and May 31, 2001.

GUIDANT considers the information contained in this report to be confidential information under 520(c) of the Act, and not releasable to the public domain for any reason.

If you have questions regarding this report, please contact me at 651-582-5224.

Sincerely,

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POST-APPROVAL ANNUAL REPORT
For
VENTAK AV and VENTAK PRIZM DR/VR
AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM

PMA NO P960040

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I. REPORT OVERVIEW

A. Scope of Report

This Post-Approval Annual Report presents performance information for the VENTAK® AV™ and VENTAK PRIZM DR/VR Automatic Implantable Cardioverter Defibrillator System as required in the Conditions of Approval Letter for PMA P960040, (Appendix A) and subsequent supplements.

Per the requirements of the Condition of Approval Letter, this annual report includes information on device performance for the period between June 1, 2000 and May 31, 2001. The cumulative survival analysis is an ongoing accumulation of data on device life since the first documented implant. The cumulative survival analysis in this report is based on the data collected since the first documented domestic implant through the period ending May 31, 2001.

The following models are included in this report:

Guidant Brand Name	Model #	Application Software
VENTAK AV AICD Pulse Generator	1810, 1815	2833
VENTAK AV II DDD AICD Pulse Generator	1820, 1825	2833
VENTAK AV II DR AICD Pulse Generator	1821, 1826	2843
VENTAK AV III DR AICD Pulse Generator	1831, 1836	2843
VENTAK VR AICD Pulse Generator	1774, 1775	2841
VENTAK PRIZM DR/VR AICD Pulse Generator	1850, 1851, 1855, 1856	2844
VENTAK PRIZM DR/HE AICD Pulse Generator	1853, 1858	2844
VENTAK PRIZM VR/HE AICD Pulse Generator	1852, 1857	2844
VENTAK PRIZM 2 DR AICD Pulse Generator	1861, 1862	2844

We have reviewed changes to each of the products listed as part of the VENTAK AV and VENTAK PRIZM DR/VR system and included this information in Section II when the change met the applicable criteria specified in 21 CFR 814.39 (b), for submission on a periodic reporting basis.

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B. Recall and Safety Alert Update

1. On February 14, 2000, Guidant initiated a recall of a subset of the VENTAK PRIZM Models 1850/1851/1855/1856 devices. The action was initiated because of a random component failure in a subset of VENTAK PRIZM AICD devices. An assessment tool was distributed to the sales representatives and used to verify if a device is susceptible to the failure. FDA classified this as a "Recall" with reference number Z-468/470-0. A request for closure was submitted on April 25, 2000. The FDA closure letter is dated October 4, 2000.

2. On April 23, 2001, Guidant issued a letter to advise physicians of a situation that potentially affects a subset of VENTAK PRIZM 1 and VENTAK PRIZM HE devices, Models 1850, 1851, 1852, 1853, 1857 and 1858. Some of these devices have automatically switched to an integrated Safety Mode because of a rare interaction between the device and a specific memory component. No specific physician action was required. FDA classified this action as a "Recall" with reference number Z-613/618-1. A request for closure was submitted on June 25, 2001.

II. DEVICE CHANGES

This section describes those device changes that have been reported in accordance with 21 CFR 814.39(a), in a PMA supplemental submission, as well as those changes meeting the criteria specified in 21 CFR 814.39(b), for submission on a periodic reporting basis.

A. PMA Supplemental Submissions

The following supplemental changes have been made to the VENTAK PRIZM system (P960040) during the time period of this report.

S17 Request approval for Version 4.0 to Application Software Model 2920 on PRx, AV and Application Software Model 2833 on AV II DDD. Submitted on July 24, 2000. Approved: December 13, 2000.

S18 Request approval for ASTRID (Atrial Sensing to Reduce Inappropriate Defibrillation) claims associated with VENTAK AV. Submitted on September 15, 2000. Approval Pending.

S19 Request approval (Real Time Review) for Torque Wrench Model 6942. Submitted on November 30, 2000. Approved: January 23, 2001.

S20 Request approval (Real Time Review) for Design modification to the header on VENTAK PRIZM Model 1851, DR/HE Model 1853 and VR Models 1850/1852. Submitted on December 22, 2000. Approved: February 1, 2001.

S21 Request approval for Version 3.3 to Application Software Model 2844 on VENTAK PRIZM. Submitted February 23, 2001. Approved: April 5, 2001.

S22 Request approval (Real Time Review) for Diagnostic/Restoration Tool Version 1.5 for Memory Interaction Safety Mode Model 2725. Submitted May 23, 2001. Approved: June 13, 2001

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B. Changes Not Included in a Submission

The following changes constitute minor manufacturing changes or other minor alterations to the device since the PMA filing date. These changes, which do not affect the safety and effectiveness of the device, do not require a PMA supplement per 21 CFR 814.39(a). These changes are therefore included in this post approval report as required in 21 CFR 814.39(b). Changes cover the period June 1, 2000 through May 31, 2001.

1. A manufacturing software test was modified to [redacted]

2. Guidant incorporated the capacitors [redacted] This is being done to standardize [redacted] All capacitors are 100% tested and meet all requirements of the capacitor specification. Device performance is unaffected by this change, and the device continues to meet the physical and functional performance requirements of Guidant device specification.

3. Guidant replaced the [redacted] Device performance is unaffected by this change, and the device continues to meet the physical and functional performance requirements of Guidant device specification.

III. BIBLIOGRAPHY and SUMMARY of STUDIES

A. Unpublished Reports Regarding the Device

Guidant is aware of the following non-clinical investigations that involve pulse generator models in this report.

1. *Evaluation of Overdrive Dual-Chamber Pacing to Reduce the Incidence of Ventricular Tachyarrhythmias with the Guidant/CPI VENTAK AV AICD System.*

[redacted]

2. *Evaluation of Incremental Detection Enhancements and Delivery of Appropriate Therapy with the Guidant VENTAK AV System.*

[redacted]

3. *Comparison of Dual- and Single-Chamber Therapy Responsiveness Using the Guidant VENTAK® AICD Family.*

[redacted]

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B. Reports in Scientific Literature Concerning the Device

Guidant conducted a literature search of English language articles in peer reviewed scientific/medical publications. Guidant searched files in the Medline database. Search descriptors were "implantable and defibrillator", biphasic cardioversion, and defibrillation shocks irrespective of manufacturer. The search did not specifically request accessories. The literature search includes articles dated between June 1, 2000 and May 31, 2001.

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IV. SYSTEM EXPERIENCE

The VENTAK AV/VR PRIZM System Experience Report is submitted in response to requirements specified in the Conditions of Approval and is found in Appendix B of this report.

V. LIFE TESTING RESULTS

In accordance with the conditions of approval for PMA 960040/S9, the capacitor life testing report for VENTAK VR is found in Appendix C of this report.

APPENDIX A: CONDITIONS OF APPROVAL

Issued: 3-4-98

CONDITIONS OF APPROVAL
FOR IMPLANTABLE DEFIBRILLATORS AND PROGRAMMERS

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401) Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Boulevard, Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

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A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement by FDA Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is

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known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

In addition to the above and in order to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use, the annual postapproval reports shall include, separately for each model number (if applicable), the following information known by or reported to the applicant:

(1) The number of pulse generators domestically implanted and the number of reported explants and deaths.

(2) A breakdown of the reported deaths into pulse generator related and non-pulse generator related.

(3) A breakdown of the reported explants into the numbers reported at end of battery life, having complications unresolvable by programming and for other reasons with safety and effectiveness issues which can be derived from the reports stated.

(4) The number of pulse generators returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion and failed, with the failure mechanisms described.

(5) A cumulative survival table for the pulse generators.

(6) The number of programmers and modules shipped and the number of returns with a breakdown into the numbers currently in analysis, operating properly and failed, with the failure mechanisms described.

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ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mix-up of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996, and requires that all manufacturers and

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importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1) May have caused or contributed to a death or serious injury; or

(2) Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) using FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc. Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336) and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturer" (FOD # 987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

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APPENDIX B: SYSTEM EXPERIENCE REPORT

VENTAK AV/VR PRIZM PULSE GENERATORS EXTERNAL DEVICES

PMA NO. P960040

Cardiac Pacemakers, Inc.
4100 Hamline Avenue North
St. Paul, MN 55112

Submission Date: August 13, 2001

Prepared and Submitted by:

Name	Signature	Title	Date
Lynn C. Zurn		Reliability Assurance Event Analyst	8-13-01
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TABLE OF CONTENTS

I. REPORT OVERVIEW

SCOPE OF REPORT

This Ventak AV/VR PRIZM Experience System Report presents performance information for the Ventak AV/VR PRIZM Pulse Generator Models and External Devices approved under PMA P960040. Device data is segregated by model number to facilitate review.

This report includes device performance information for the period between June 1, 2000 through May 31, 2001. The cumulative survival analysis is an ongoing accumulation of data on device life since the first documented implant.

Model	Device Name
1810	Ventak AV, AICD Pulse Generator
1815	Ventak AV, AICD Pulse Generator
1820	Ventak AV II DDD, AICD Pulse Generator
1825*	Ventak AV II DDD, AICD Pulse Generator
1821	Ventak AV II DR, AICD Pulse Generator
1826	Ventak AV II DR, AICD Pulse Generator
1831	Ventak AV III DR, AICD Pulse Generator
1836	Ventak AV III DR , AICD Pulse Generator
1774	Ventak VR, AICD Pulse Generator
1775	Ventak VR, AICD Pulse Generator
1850	Ventak PRIZM DR/VR, Pulse Generator
1851	Ventak PRIZM DR/VR, Pulse Generator
1852	Ventak PRIZM DR/VR, Pulse Generator
1855*	Ventak PRIZM DR/VR, Pulse Generator
1856	Ventak PRIZM DR/VR, Pulse Generator
1853	Ventak PRIZM DR/HE, Pulse Generator
1858	Ventak PRIZM DR/HE, Pulse Generator
1852	Ventak PRIZM VR/HE, Pulse Generator
1857	Ventak PRIZM VR/HE, Pulse Generator
1861	Ventak PRIZM 2 DR/VR, Pulse Generator
1862*	Ventak PRIZM 2 DR/VR, Pulse Generator
2833	Software Disk for Ventak AV & AV II DDD Pulse Generators
2843	Software Disk for Ventak AV II & III DR Pulse Generators
2841	Software Disk for Ventak VR Pulse Generators
2844	Software Disk for Ventak PRIZM DR/VR Pulse Generators

(These models had no activity during this report period.)

II. DEVICE EXPERIENCE

The following information is submitted in response to requirements as specified in the Conditions of Approval. The numbers reported here are for devices distributed in the United States. Data used to derive these reports were obtained from the company's databases. All events tabulated in this report were reviewed for Medical Device Reporting (MDR) filing at the time GUIDANT received information that a reportable event may have occurred. Where appropriate, MDRs were filed.

Data are reported separately for each model as specified in the Conditions of Approval.

The cumulative survival tables in this report were prepared using standard life table techniques (see Cutler and Ederer, 1958, J Chron. Dis., 8:6). The follow-up experience has been divided into three-month intervals for reporting purposes. For each interval, a calculation has been made of the number of units at risk during the interval. The number of units at risk was found by starting with the number of devices that entered the interval and correcting for the units that failed, or were taken out-of-service for a reason not related to the device.

The number of devices that failed during an interval, divided by the number at risk, result in an estimate of the probability of failure during the interval.

Please note that the Cumulative Survival Percentage provided in this report is affected only by those units that were returned to GUIDANT, analyzed, determined to be defective and classified as such by Reliability Assurance. Units with induced damage (such as "terminal pin bent"), that are considered out of specification even though they are operating within specification, do not factor into the reported Cumulative Survival Percent.

For each interval, the probability of failure during the interval is subtracted from one to give the probability of survival in the interval. Survival probability through a series of intervals is obtained as the product of individual survival probabilities.

Please note, that the total number of units reported on the cumulative survival report table may be higher than the total number of units reported under FDA Reporting Requirement #1. The report period for FDA Reporting Requirement #1 represents only a portion of the total number of units implanted for that model, while cumulative survival represents all devices implanted since release for clinical use.

VENTAK AV, AICD PULSE GENERATOR, MODEL 1810

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	91
(c)	Total units in patients who reportedly died in report period	28

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device related	28
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		91
Elective Replacement		24
Erosion		1
Heart Transplant		2
Infection		2
Normal ERI		19
Other observation/Complication		1
Product Performance Issue**		9
Communication/Telemetry Issue	3	
Diagnostic/Data Issue	1	
Sensing/Detection Issue	5	
System to Patient Interface Issue	3	
Therapy Delivery/Effectiveness Issue	4	
Unknown or Insufficient information provided		31
Upgrade		2

***Each Out-of –Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause		43
Out of Specification		6
Arcing damage, Module output high power	1	
Induced	2	
Overstress, high energy	1	
Solder joint, cracked	1	
Undetermined/inconclusive	1	
Unit Meet Specifications		37

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for VENTAK AV AICD Pulse Generator, Model 1810

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	99.82%	0.07%
3 – 6	[redacted]	99.77%	0.08%
6 – 9	[redacted]	99.71%	0.09%
9 – 12	[redacted]	99.60%	0.10%
12 – 15	[redacted]	99.57%	0.11%
15 – 18	[redacted]	99.51%	0.12%
18 – 21	[redacted]	99.48%	0.12%
21 – 24	[redacted]	99.39%	0.13%
24 – 27	[redacted]	99.36%	0.13%
27 – 30	[redacted]	99.21%	0.15%
30 – 33	[redacted]	99.14%	0.16%
33 – 36	[redacted]	99.08%	0.16%
36 – 39	[redacted]	99.01%	0.17%
39 – 42	[redacted]	99.01%	0.17%
42 – 45	[redacted]	98.95%	0.18%
45 – 48	[redacted]	98.95%	0.18%

VENTAK AV AICD PULSE GENERATOR, MODEL 1720

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	6
(c)	Total units in patients who reportedly died in report period	1

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its devices may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the device may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device related	1
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)	6
Heart Transplant	1
Normal ERI	2
Unknown of insufficient information provided	3

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as leads not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) not every device taken out-of-service is returned for analysis, and 2) pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	3
Unit Meets Specification	3

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for VENTAK AV AICD Pulse Generator, Model 1815

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 - 3	[redacted]	100.00%	0.00%
3 - 6	[redacted]	100.00%	0.00%
6 - 9	[redacted]	100.00%	0.00%
9 - 12	[redacted]	100.00%	0.00%
12 - 15	[redacted]	100.00%	0.00%
15 - 18	[redacted]	99.36%	0.63%
18 - 21	[redacted]	99.36%	0.63%
21 - 24	[redacted]	98.70%	0.91%
24 - 27	[redacted]	98.70%	0.91%
27 - 30	[redacted]	98.70%	0.91%
30 - 33	[redacted]	98.70%	0.91%
33 - 36	[redacted]	98.70%	0.91%
36 - 39	[redacted]	98.70%	0.91%
39 - 42	[redacted]	98.70%	0.91%
42 - 45	[redacted]	98.70%	0.91%

VENTAK AV II DDD AICD PULSE GENERATOR, MODEL 1820

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	4
(c)	Total units in patients who reportedly died in report period	5

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its devices may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device related	5
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)	4
Elective Replacement	1
Normal ERI	1
Unknown of insufficient information provided	2

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as leads not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) not every device taken out-of-service is returned for analysis, and 2) pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	4
Out of Specification Cracked, structure or outer body, Analog hybrid Assy 1	1
Unit Meet Specifications	3

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for VENTAK AV II DDD AICD Pulse Generator, Model 1820

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	100.00%	0.00%
3 – 6	[redacted]	99.82%	0.18%
6 – 9	[redacted]	99.82%	0.18%
9 - 12	[redacted]	99.82%	0.18%
12 - 15	[redacted]	99.82%	0.18%
15 - 18	[redacted]	99.82%	0.18%
18 – 21	[redacted]	99.82%	0.18%
21 – 24	[redacted]	99.82%	0.18%
24 – 27	[redacted]	99.62%	0.27%
27 – 30	[redacted]	99.62%	0.27%
30 – 33	[redacted]	99.62%	0.27%
33 – 36	[redacted]	99.62%	0.27%
36 – 39	[redacted]	99.62%	0.27%
39 – 42	[redacted]	99.62%	0.27%

VENTAK AV II DR AICD PULSE GENERATOR, MODEL 1821

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	83
(c)	Total units in patients who reportedly died in report period	36

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its devices may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the device may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	36
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		83
Dissatisfed with product		1
Coincident Removal		3
Elective Replacement		27
Heart Transplant		3
Infection		2
Normal ERI		7
Product Performance Issue**		10
Communication/Telemetry Issue	2	
Diagnostic/ Data Issue	4	
Mechanical Connection Issue	1	
Premature Battery Depletion	2	
Sensing/ Detection Issue	2	
System to Patient Interface Issue	2	
Therapy Delivery/ Effectiveness Issue	2	
Unknown or Insufficient Information provided		28
Upgrade		2

***Each Out-of--Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as leads not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) not every device taken out-of-service is returned for analysis, and 2) pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause		52
Out of Specification		16
Transfer Error Code	1	
Cracked substrate hybrid assy Analog AVII	1	
Depletion, premature, undetermined	1	
Induced	8	
Logic Error	1	
Overstress, high energy	1	
Shorted, module output high power	1	
Solder Joint, poor quality	1	
Undetermined/inconclusive	1	
Unit Meet Specifications		36

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for VENTAK AV II DR AICD Pulse Generator, Model 1821

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	99.96%	0.03%
3 – 6	[redacted]	99.84%	0.06%
6 – 9	[redacted]	99.60%	0.09%
9 – 12	[redacted]	99.58%	0.09%
12 – 15	[redacted]	99.54%	0.10%
15 – 18	[redacted]	99.54%	0.10%
18 – 21	[redacted]	99.52%	0.10%
21 – 24	[redacted]	99.50%	0.10%
24 – 27	[redacted]	99.50%	0.10%
27 – 30	[redacted]	99.45%	0.11%
30 – 33	[redacted]	99.40%	0.11%
33 – 36	[redacted]	99.29%	0.13%
36 – 39	[redacted]	99.29%	0.13%

VENTAK AV II DR AICD PULSE GENERATOR, MODEL 1826

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	7
(c)	Total units in patients who reportedly died in report period	1

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its devices may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the device may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	1
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)	7
Normal ERI	2
Unknown of insufficient information provided	5

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) not every device taken out-of-service is returned for analysis, and 2) pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	0

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for VENTAK AV II DR AICD Pulse Generator, Model 1826

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	100.00%	0.00%
3 – 6	[redacted]	100.00%	0.00%
6 – 9	[redacted]	100.00%	0.00%
9 – 12	[redacted]	100.00%	0.00%
12 – 15	[redacted]	100.00%	0.00%
15 – 18	[redacted]	100.00%	0.00%
18 – 21	[redacted]	100.00%	0.00%
21 – 24	[redacted]	100.00%	0.00%
24 – 27	[redacted]	100.00%	0.00%
27 – 30	[redacted]	100.00%	0.00%
30 – 33	[redacted]	100.00%	0.00%
33 – 36	[redacted]	100.00%	0.00%

VENTAK AV III DR AICD PULSE GENERATOR, MODEL 1831

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	188
(c)	Total units in patients who reportedly died in report period	84

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its devices may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the device may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	84
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

   Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

See table of following page for details

Out-of-Service Units (as indicated by the user)		188
Coincident Removal		2
Elective Replacement		21
Infection		12
Normal ERI		2
Other Observation/ complication		1
Heart Transplant		14
Product Performance Issue**		78
Communication/Telemetry Issue	40	
Contamination Issue	1	
Diagnostic/Data Issue	57	
Mechanical Connection Issue	1	
Premature Battery Depletion	14	
Sensing/ Detection Issue	4	
System to Patient Interface Issue	8	
Therapy Delivery/Effectiveness Issue	21	
Product Performance Issue, Never Implanted		1
Unknown or Insufficient information provided		56
Upgrade		1

***Each Out-of-Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) not every device taken out-of-service is returned for analysis, and 2) pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	144
Analysis Pending	18

Out of Specification		67
Degraded, parameter shift out of spec	3	
Dendritic growth	1	
Dendtritic growth, EPROM	1	
Dendritic growth, eprom encoded	2	
Dendritic growth, hybrid assembly	12	
Depletion, premature, undetermined	1	
Excessive current, undetermined	1	
Fracture, non specific, inductor power	1	
Fracture, non specific, LDFrame	1	
Induced	9	
Leaky, Cap Tant Module Dual	2	
Leaky, Cap, Tantalum	2	
Leaky Hybrid assembly	1	
Leaky, Trans Die Mosfet NCHAN Sense	1	
Logic error	1	
Logic error, Firmware/Software	3	
Memory/address value(s) corrupted	1	
Severed, LD Frame/ASIC Telem	1	
Shorted, dendritic growth, Eprom Encoded	1	
Shorted, dendritic growth, hybrid assembly	1	
Shorted, foreign material, XFMR Toroid	1	
Solder joint, electrically intermittent	2	
Undetermined/inconclusive	21	
Undetermined/inconclusive Hybrid assembly	1	
Unit Meet Specifications		59

(b) Analysis results of preimplant units returned for cause	3
Out of Specification Induced 1	1
Unit Meet Specifications	2

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak AV III DR AICD Pulse Generator, Model 1831

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 - 3	[redacted]	99.90%	0.03%
3 - 6	[redacted]	99.80%	0.05%
6 - 9	[redacted]	99.63%	0.06%
9 - 12	[redacted]	99.38%	0.08%
12 - 15	[redacted]	99.16%	0.09%
15 - 18	[redacted]	99.03%	0.10%
18 – 21	[redacted]	98.86%	0.11%
21 – 24	[redacted]	98.77%	0.12%
24 – 27	[redacted]	98.58%	0.14%
27 – 30	[redacted]	98.42%	0.16%

VENTAK AV III DR AICD, PULSE GENERATOR, MODEL 1836

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	12
(c)	Total units in patients who reportedly died in report period	4

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its devices may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the device may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	4
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		12
Elective Replacement		4
Infection		1
Product Performance Issue**		1
Communication/ Telemetry Issue	1	
System to Patient Interface Issue	1	
Unknown or insufficient information provided		5
Upgrade		1

***Each Out-of –Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) not every device taken out-of-service is returned for analysis, and 2) pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	5
Analysis Pending	1
Unit Meet Specifications	4

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak AV III DR AICD Pulse Generator, Model 1836

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 - 3	[redacted]	100.00%	0.00%
3 - 6	[redacted]	100.00%	0.00%
6 - 9	[redacted]	99.22%	0.78%
9 - 12	[redacted]	99.22%	0.78%
12 - 15	[redacted]	99.22%	0.78%
15 - 18	[redacted]	99.22%	0.78%
18 – 21	[redacted]	99.22%	0.78%
21 – 24	[redacted]	99.22%	0.78%
24 – 27	[redacted]	99.22%	0.78%

VENTAK VR 3.2 AICD PULSE GENERATOR, MODEL 1774

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	16
(c)	Total units in patients who reportedly died in report period	8

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	8
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		16
Elective Replacement		6
Heart Transplant		2
Infection		1
Product Performance Issue **		2
Communication//Telemetry Issue	1	
Diagnostic/Data Issue	1	
Unknown or insufficient information provided		4
Upgrade		1

***Each Out-of –Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4

(a) Analysis results of explanted units returned for cause		12
Out of Specification		3
Arcing damage, XFMR Toroid	1	
Induced	1	
Undetermined/inconclusive	1	
Unit Meet Specifications		9

(b) Analysis results of preimplant units returned for cause	1
Unit Meet Specifications	1

66

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for VENTAK VR 3.2 AICD Pulse Generator, Model 1774

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 - 3	[redacted]	99.89%	0.11%
3 - 6	[redacted]	99.77%	0.16%
6 - 9	[redacted]	99.65%	0.20%
9 - 12	[redacted]	99.65%	0.20%
12 - 15	[redacted]	99.65%	0.20%
15 - 18	[redacted]	99.65%	0.20%
18 – 21	[redacted]	99.65%	0.20%
21 – 24	[redacted]	99.65%	0.20%

VENTAK VR 6.1 AICD PULSE GENERATOR, MODEL 1775

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	7
(c)	Total units in patients who reportedly died in report period	1

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	1
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)	7
Elective Replacement	3
Unknown or insufficient information provided	4

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	6
Unit Meet Specifications	6

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for VENTAK VR 6.1 AICD Pulse Generator, Model 1775

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 - 3	[redacted]	100.00%	0.00%
3 - 6	[redacted]	100.00%	0.00%
6 - 9	[redacted]	100.00%	0.00%
9 - 12	[redacted]	100.00%	0.00%
12 - 15	[redacted]	100.00%	0.00%
15 - 18	[redacted]	100.00%	0.00%
18 – 21	[redacted]	100.00%	0.00%
21 – 24	[redacted]	100.00%	0.00%

VENTAK PRIZM DR/VR PULSE GENERATOR, MODEL 1850

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	135
(c)	Total units in patients who reportedly died in report period	126

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	126
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

   Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

See Table on Following page for details

Out-of-Service Units (as indicated by the user)		135
Elective Replacement		26
Electively not Used		1
Erosion		2
Heart Transplant		9
Infection		21
Normal ERI		2
Other Observation/Complication		3
Product Performance Issue**		22
Communication/Telemetry Issue	3	
Diagnostic/Data Issue	19	
Mechanical Connection Issue	2	
Premature Battery Depletion	4	
Sensing/ Detection Issue	1	
System to Patient Interface Issue	9	
Therapy Delivery/ Effectiveness Issue	3	
Recall/Advisory		1
Unknown or insufficient information provided		44
Upgrade		4

***Each Out-of-Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause		65
Analysis Pending		1
Out of Specification		29
Degraded, parameter shift, Hybrid	1	
Degraded, parameter shift, Transistor	1	
Induced	5	
Leaky, Cap Chip Tant, Module 5	1	
Logic Error	1	
Memory/address value(s) corrupted	18	
Trace or via, open, Hybrid MDL	1	
Undetermined/inconclusive	1	
Unit Meet Specifications		35

(b) Analysis results of preimplant units returned for cause		91
Analysis Pending		2
Out of Specification		22
Degraded, parameter shift, Trans-Die Mosfet	1	
Depletion, premature, undetermined	1	
Induced	11	
Memory/address value(s) corrupted	5	
Trace or via, open, hybrid MDL	2	
Undetermined/inconclusive	2	
Unit Meet Specifications		67

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM DR/VR Pulse Generator, Model 1850

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	99.83%	0.05%
3 – 6	[redacted]	99.59%	0.09%
6 – 9	[redacted]	99.53%	0.10%
9 – 12	[redacted]	99.53%	0.10%
12 – 15	[redacted]	99.53%	0.10%

VENTAK PRIZM DR/VR PULSE GENERATOR, MODEL 1851

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	180
(c)	Total units in patients who reportedly died in report period	294

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	293
• Device Related (1851/309036) see below FDA # 2124215000200002428	1

Guidant received information that the patient with this Implantable Cardioverter Defibrillator (ICD) expired 2 days following the implant of this device. It was noted that the device "went off" continuously for approximately 10 minutes; however, it was not noted as to whether or not this occured prior to or after the patient's death. Guidant made several attempts to obtain additional information regarding the exact cause of the patient's death and the performance of the device; however, additional information was unable to be obtained. The device was not returned for analysis as it was buried with the patient. Guidant will submit additional information if it becomes available. An MDR death report was submitted November 1, 2000.

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		180
Elective Replacement		17
Heart Transplant		13
Infection		47
Normal ERI		3
Other Observation/Complication		4
Product Performance Issue**		37
Communication/Telemetry Issue	1	
Diagnostic/ Data Issue	40	
Mechanical Connection Issue	17	
Physical Damage	1	
Premature Battery Depletion	2	
Sensing/Detection Issue	6	
System to Patient Interface Issue	15	
Therapy Delivery/Effectiveness Issue	4	
Recall/Advisory		2
Unknown or insufficient information provided		55
Upgrade		2

***Each Out-of –Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause		109
Analysis Pending		1
Out of Specification		55
Degraded, parameter shift out of spec	1	
Foreign Material present, header ICD	1	
Induced	15	
Leaky, Cap Tant Module dual	1	
Logic error	1	
Memory/address value(s) corrupted	24	
Open, electrically, hybrid MDL	2	
Shorted, contact with case	2	
Solder joint, cracked	1	
Solder joint, electrically intermittent	1	
Trace or via open, Hybrid MDL	6	
Unit Meet Specifications		53

(b) Analysis results of preimplant units returned for cause		107
Analysis Pending		3
Out of Specification		39
Foreign material present, header ICD	1	
Induced	23	
Memory/address value(s) corrupted	9	
Open, electrically	1	
Stuck, set screw socket head half dog	1	
Trace or via, open, hybrid MDL	2	
Undetermined/inconclusive	2	
Unit Meet Specifications		65

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM HE VR Pulse Generator, Model 1851

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	99.87%	0.04%
3 – 6	[redacted]	99.72%	0.05%
6 – 9	[redacted]	99.66%	0.06%
9 – 12	[redacted]	99.61%	0.07%
12 – 15	[redacted]	99.61%	0.07%

VENTAK PRIZM DR/VR PULSE GENERATOR, MODEL 1856

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	0
(c)	Total units in patients who reportedly died in report period	0

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	0
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)	0

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	0

(b) Analysis results of preimplant units returned for cause	0

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM Pulse Generator, Model 1856

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	100.00%	0.00%
3 – 6	[redacted]	100.00%	0.00%
6 – 9	[redacted]	100.00%	0.00%
9 – 12	[redacted]	100.00%	0.00%

VENTAK PRIZM DR/HE PULSE GENERATOR, MODEL 1853

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	18
(c)	Total units in patients who reportedly died in report period	34

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	34
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		18
Heart Transplant		6
Infection		6
Product Performance Issue**		2
Diagnostic/ Data Issue	3	
Mechanical Connection Issue	3	
System to Patient Interface Issue	2	
Recall/Advisory		1
Unknown or Insufficient information provided		3

***Each Out-of –Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause		12
Out of Specification		5
Induced	4	
Trace or via, open hybrid MDL	1	
Unit Meet Specifications		7

(b) Analysis results of preimplant units returned for cause		7
Out of Specification		3
Induced	2	
Memory/address value(s) corrupted	1	
Unit Meet Specifications		4

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM DR/HE Pulse Generator, Model 1853

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	99.89%	0.11%
3 – 6	[redacted]	99.89%	0.11%
6 – 9	[redacted]	99.89%	0.11%

VENTAK PRIZM DR/HE PULSE GENERATOR, MODEL 1858

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   * GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	1
(c)	Total units in patients who reportedly died in report period	1

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	1
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)	1
Elective Replacement	1

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	0

(b) Analysis results of preimplant units returned for cause		4
Out of Specification		1
Foreign material present	1	
Unit Meet Specification		3

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM DR/HE Pulse Generator, Model 1858

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	100.00%	0.00%
3 – 6	[redacted]	100.00%	0.00%
6 – 9	[redacted]	100.00%	0.00%

VENTAK PRIZM VR/HE PULSE GENERATOR, MODEL 1852

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	5
(c)	Total units in patients who reportedly died in report period	2

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	2
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		5
Heart Transplant		1
Product Performance Issue**		2
Diagnostic/Data Issue	3	
Unknown or Insufficient information provided		2

***Each Out-of –Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause		1
Out of Specification		1
Memory/address value(s) corrupted	1	

(b) Analysis results of preimplant units returned for cause	0

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5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM VR/HE Pulse Generator, Model 1852

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	100.00%	0.00%
3 – 6	[redacted]	99.21%	0.79%

VENTAK PRIZM DR/HE PULSE GENERATOR, MODEL 1857

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	1
(c)	Total units in patients who reportedly died in report period	3

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	3
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)	1
Elective Replacement	1

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause	1
Unit Meet Specification	1

(b) Analysis results of preimplant units returned for cause	1
Out of Specification Memory/address value(s) corrupted 1	1

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM VR/HE Pulse Generator, Model 1857

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	100.00%	0.00%
3 – 6	[redacted]	100.00%	0.00%

VENTAK PRIZM 2 DR/VR PULSE GENERATOR, MODEL 1861

1. *FDA Reporting Requirement: The number of devices domestically implanted and the number of reported explants* and deaths.*

   *GUIDANT uses the term "out-of-service" rather than "explanted" because GUIDANT does not always know if the device was removed from the body.

(a)	Total units implanted in report period	[redacted]
(b)	Total units reported explanted (out-of-service) in report period (excluding reported deaths)	50
(c)	Total units in patients who reportedly died in report period	79

2. *FDA Reporting Requirement: A breakdown of the reported deaths into device related and non-device related.*

   GUIDANT used the company's Medical Device Reporting procedure to determine death events that met the definition of "Device Related."

   A death is reported as "Device Related" when GUIDANT received or otherwise became aware of information that reasonably suggested that one of its leads may have caused or contributed to the death. In addition, a death is reported as "Device Related" if the death was believed to be the result of user error when the information reasonably suggested that the lead may have caused or contributed to the death.

   Submission of a report as "Device Related" does not constitute an admission that the manufacturer, product, medical personnel, or user facility caused or contributed to the death.

• Non-Device Related	79
• Device Related	0

3. *FDA Reporting Requirement: A breakdown of the reported explants into the numbers reported as at end of battery life, having complications unresolvable by programming, and for other reasons with safety and effectiveness issues which can be derived from the reports stated.*

Please note that GUIDANT designates units as "out-of-service" rather than "explanted." When an out-of-service device is explanted and returned to GUIDANT, it is tabulated in the analysis section (FDA Reporting Requirement #4).

Out-of-Service Units (as indicated by the user)		50
Elective Replacement		4
Electively not Used		3
Heart Transplant		1
Infection		12
Other observation/complication		4
Product Performance Issue**		11
Communication/Telemetry Issue	1	
Diagnostic/ Data Issue	6	
Mechanical Connection Issue	5	
Premature Battery Depletion	1	
Sensing/ Detection Issue	3	
System to patient Interface Issue	11	
Therapy Delivery/ Effectiveness Issue	2	
Unknown or Insufficient information provided		15

***Each Out-of–Service unit with a product performance issue may have more than one observation. Therefore, the number of units with product performance issues may be less that the number of observations.*

4. *FDA Reporting Requirement: The number of devices returned to the applicant for cause from domestic sources with a breakdown into the numbers currently in analysis, operating properly, at normal battery depletion, and failed, with the failure mechanisms described.*

Please note that in this section GUIDANT is reporting devices that have been explanted and returned for analysis, as well as devices not implanted before return. Devices in the later category are considered pre-implant units and are reported separately.

The number of devices discussed in this section will differ from those discussed in FDA Reporting Requirement #3 for two reasons: 1) Not every device taken out-of-service is returned for analysis, and 2) Pre-implant devices are included in FDA Reporting Requirement #4.

(a) Analysis results of explanted units returned for cause		22
Analysis Pending		3
Out of Specification		6
Cracked, RC Network	1	
Degraded, parameter shift out of spec	1	
Induced	3	
Leaky, Cap Tantalum	1	
Unit Meet Specifications		13

(b) Analysis results of preimplant units returned for cause		58
Analysis Pending		6
Out of Specification		8
Induced	8	
Unit Meet Specification		44

5. *FDA Reporting Requirement: A cumulative survival table for the devices.*

The Cumulative Survival Analysis for Ventak PRIZM 2 DR/VR Pulse Generator, Model 1861

AGE in MONTHS	NUMBER of UNITS	SURVIVAL RATE	STANDARD ERROR
0 – 3	[redacted]	99.98%	0.02%
3 – 6	[redacted]	99.88%	0.07%

EXTERNAL PRODUCTS EXPERIENCE

I.FDA Reporting Requirement: The number of programmers and modules shipped and the number of returns with a breakdown in to the numbers currently in analysis, operating properly and failed, with the failure mechanisms described.

SOFTWARE DISK FOR THE VENTAK AV & AV II DDD PULSE GENERATORS, MODEL 2833

(a)	Total units shipped in report period		[redacted]
(b)	Analysis results of explanted units returned for cause		101
	Scrap	80	
	Unit Meet Specifications	21	

SOFTWARE DISK FOR THE VENTAK AV II & III DR PULSE GENERATORS, MODEL 2843

(a)	Total units shipped in report period		[redacted]
(b)	Analysis results of total units returned in report period		88
	Scrap	88	

SOFTWARE DISK FOR THE VENTAK VR PULS E GENERATORS, MODEL 2841

(a)	Total units shipped in report period		[redacted]
(b)	Analysis results of total units returned in report period		107
	Scrap	81	
	Unit Meets Specifications	26	

SOFTWARE DISK FOR THE VENTAK PRIZM DR/VR PULSE GENERATORS, MODEL 2844

(a)	Total units shipped in report period	[redacted]
(b)	Analysis results of total units returned in report period	236
	Scrap	194
	Analysis Pending	2
	Out of Specification Degraded, parameter out of spec 1	1
	Unit Meet Specification	39

APPENDIX C: CAPACITOR LIFE TEST REPORT for VENTAK VR

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GUIDANT

[redacted], Revision C

Component Evaluation Test Report
High Energy Capacitor
Storage Test- Interim Test Results
CPI Part Number [redacted]

Manufacturer: Guidant
Project: Ventak VR
Responsible Department: Supplier Development

Authored By:

Maureen Esteb		Component Engineer	7/10/01
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21 Whole Page Redactions