EXHIBIT D

Report

of the

INDEPENDENT PANEL OF GUIDANT CORPORATION

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March 20, 2006

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The undersigned participated in the review process and preparation of this Report of the Independent Panel of Guidant Corporation. The Report is a consensus statement. No minority statements were submitted.

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PREAMBLE

Implantable cardiovascular devices have evolved as a major class of medical products used for the management of cardiovascular disorders. This class of medical devices includes a broad range of categories, such as intravascular stents, artificial valves, hemodynamic support devices, as well as pacemakers, defibrillators, and their related lead systems. All categories of such devices are subject to the limitations inherent to any manufactured product, including unanticipated flaws in design, random errors during the manufacturing process, random component failures, and malfunctions acquired during the useful life of the devices. In the case of electrically active devices, programming errors also might result in malfunctions under certain circumstances. Such errors include both those that could not have been predicted and those that could have been predicted with a better understanding of the design, manufacturing, and device use. All of these categories of malfunctions and failures are superimposed upon the potential stresses of the human body environment, and in the case of electrically active systems, the expected battery depletion over time.

In order to effectively identify and manage device defects as part of their Quality Systems, manufacturers are required by the FDA to implement strategies for the design and manufacture of highly reliable devices and the surveillance of their products in the field. They must also develop methods for identifying and correcting defects that are potentially or manifestly hazardous. Policies for appropriate communication of information about defects to prescribing physicians and the relevant populations of patients are additional obligations. Under certain circumstances, the latter operate in parallel with, and in addition to, the regulatory requirements for reporting to the FDA and other regulatory bodies.

Beginning in May 2005, Guidant Corporation attracted a great deal of attention in the public media and medical community as a result of reports of a series of previously undisclosed defects in one category of their implantable products, namely pacemakers and defibrillators, manufactured by their Cardiac Rhythm Management (CRM) business. As information evolved, it became apparent that the CRM business of Guidant Corporation was aware of, evaluating, and mitigating the issues related to a number of these defects in a certain group of defibrillators during the period of more than three years from the point in time at which the first of this series of defects was recognized. In accordance with their procedures at that time, information about these defects had been reported to the FDA, as required by regulations, but had not been communicated to the Guidant Management Committee, to the public or

potentially affected patients.

The reported death of one individual attributed to a previously identified defect in a defibrillator, in conjunction with delayed visibility to the public, generated serious criticisms of Guidant Corporation in the public media, particularly in regard to failure to communicate in what was interpreted to be a timely fashion. Guidant's publicly stated position was that they had attempted to balance the benefit of disclosure against potentially negative consequences, and defended their position of non-disclosure as medically appropriate. This response was judged unacceptable by public media and some segments of the medical population, and negative commentaries about Guidant Corporation's policies and procedures in regard to defect reporting continued through the summer and fall of 2005.

In the wake of abruptly increasing criticism, Guidant Corporation announced in June 2005, that it intended to commission an Independent Panel charged with the responsibility of studying, analyzing and evaluating the Policies and Procedures of the CRM business, in regard to postmarket device performance, analysis of defects, surveillance of marketed devices, and communication of deviations to physicians, patients, and the general public. The mandate of the Independent Panel of Guidant Corporation was to carry out this review and analysis and provide recommendations for improving performance in regard to surveillance for low frequency events and communications to physicians and patients. The details of the history of the Independent Panel, including its creation, mission, charter, membership, procedures, and operations are provided in this Report. Among the commitments made by Guidant Corporation to the Independent Panel were unencumbered access to relevant corporate documents and personnel, and independence of function.

This document constitutes the Report of the findings and recommendations of the Independent Panel of Guidant Corporation. The design of the Report includes an initial summary of general observations and a series of problems requiring attention. These serve the function of an executive summary, providing focus on the major findings and recommendations. This is followed by a detailed description of observations of the multiple elements that the Independent Panel studied in all of the relevant segments of Guidant Corporation that deal with defibrillators and pacemakers. Detailed statements about the recommendations and their rationale follow, and are supported by the Independent Panel's findings. The next section cites relevant reference material that can provide detailed background information for the interested reader. Finally, the Appendix provides a series of technical descriptions of strategies for implementing the major recommendations.

We anticipate that implementation of the Independent Panel's recommendations, which are based upon the analysis and integration of the information made available to it, will provide better methods for identifying, mitigating, and communicating device malfunctions. Although many of the details of the recommendations are specific to Guidant Corporation, the general principles embodied in the statements will likely be applicable to the pacemaker and implantable defibrillator industry generally. Inherent to all the recommendations of the Independent Panel are three fundamental assumptions:

- Manufactured devices can never be 100 percent free of design or manufacturing flaws, but for products for which the consequence of a failure can be a fatal event, the design tolerances and postmarket surveillance strategies should be intended to move failure rates as close to zero as possible.

- Physicians have a need to know about the performance features of specific devices in a form that is understandable and clinically useful.

- Patients have a right to access such information in order to make informed decisions about risks and benefits, and to formulate expectations.

Our recommendations are generally intended to provide a smooth and effective interface between the manufacturer, prescriber, and recipient of these devices.

NOTE REGARDING TERMINOLOGY

Within the device industry generally, there are inconsistencies in the language used to address the problem of malfunctions and failures. For the purpose of this document, the Independent Panel has adopted a uniform language standard which may be at variance with some of the usages in other venues. The language variations include terms such as components versus devices, failure versus malfunction, and manifest versus potential risk. We have adopted the following language for use in this Report:

I. RELIABILITY

A. DEVICE: The completed manufactured product, including all of its components (with the exception of its lead systems), in a physical form that is ready for implantation in a patient.

1. Device Failure: The inability of the device to provide therapy that is intended for the survival or avoidance of major medical morbidities.

2. Device Malfunction: A deviation from the intended function or response to a clinical event that the device is intended to provide. Malfunctions in the extreme may be device failures as defined above, or may be of lesser clinical significance but still requiring mitigation.

B. COMPONENT: A manufactured element, or designed software, within a device, a failure or malfunction of which might lead to a device malfunction or failure.

1. Component Design Flaw: A design feature of a component or components that creates a systematic risk of failure.

2. Component Manufacturing Defect: A manufacturing error that can result in a component malfunction.

3. Component Interaction Risk: A design feature that results in an interaction between components resulting in a malfunction, even though the components in isolation function properly.

C. CATEGORIES OF COMPONENT OR DEVICE DEFECT

1. Random: A defect unique to a specific component that causes non-repetitive malfunctions or failures. This may be due to manufacturing error during construction of a single device or a single defective component.

2. Systematic: Repetitive malfunctions or failures due to a design flaw or inherent component defect.

D. CATEGORIES OF RISK

1. Manifest vs potential life-threatening events: "Manifest" refers to the occurrence of one or more actual fatal or near-miss events as a result of device failure or malfunction. "Potential" refers to a flaw or defect that creates a realistic potential for a fatal or near-miss event in the future, if not mitigated or replaced.

2. Population risk versus individual risk: Distinction between a statistical statement of risk probability among a defined universe of patients and risk consequences for an individual.

II. SURVEILLANCE

A. VOLUNTARY REPORTING: Reporting of product variances at the option of physicians, patients, facilities, manufacturers, or distributors.

B. MANDATORY REPORTING: Regulatory agency requirement for facilities, manufacturers, or distributors to report product variances.

C. PASSIVE SURVEILLANCE: A process that relies upon information reported to a manufacturer or regulatory agency by a consumer or user, in the absence of a process that seeks disclosure.

D. ACTIVE SURVEILLANCE: A policy or procedure that proactively tracks device performance and/or variances.

III. COMMUNICATION

A. TRANSPARENCY: Availability of information to stakeholders regarding matters that affect their interests. For the mission of the Independent Panel of Guidant Corporation, stakeholders include the relevant health care providers, patients, family members, and regulatory agencies.

1. Passive Transparency: Availability of information upon the volition of the stakeholder through public access sources. Examples pertinent the mission of the Independent Panel of Guidant Corporation include continuously updated postings on the Guidant web site and routine publishing of information in the product performance reports.

2. Active Transparency: An active effort to direct relevant information to specific stakeholders. Directed communication of information to targeted audiences, such as physicians and patients, using methods such as press releases, "Dear Doctor" or "Dear Patient" letters, or specific performance postings on the web site.

3. Forced Transparency: Release of information by outside parties, such as regulators, activists, or the media, about an issue or concern of potential interest to the public or to other stakeholders.

B. RELIABILITY AND PERFORMANCE COMMUNICATION: Techniques used to provide information to stakeholders about anticipated and actual product safety, reliability and performance, including deviations between projected and actual performance.

1. Proactive Communication Policy: An effort to provide information in anticipation of potential events of relevance to stakeholders. In the case of medical devices, this includes statements that any manufactured device may have a low rate of unexpected malfunctions or performance failures and the creation of a base of continuously updated performance information, accessible to stakeholders.

2. Reactive Communication Policy: Information provided in response to an event internal or external to the institution. In the case of medical devices, this often involves reporting of previously undisclosed information, in response to circumstances that make disclosure mandatory.

TABLE OF CONTENTS

Section I

EXECUTIVE SUMMARY

A. Overview of Observations

1. Corporate Structure and Function

Guidant Corporation consists of four core businesses in the biomedical industry (Cardiac Rhythm Management, Cardiac Surgery, Endovascular Solutions, and Vascular Intervention), and a combined sales organization, Guidant Sales Corporation. The four core businesses evolved from independently operating subsidiaries of Eli Lilly when Guidant Corporation was formed in 1994 and emerged from Eli Lilly as a separate corporation in 1995.

While they present themselves under the "Guidant" banner to the general public, including physicians, patients, and business stakeholders, the manufacturing and marketing activities of each of the core businesses function nearly independently, as do research and development and postmarket surveillance and communications. They are tied together at the corporate level by a structure intended to exert oversight, but little direct hands-on management. The oversight function is manifest through corporate officers, who meet with senior officers of each of the businesses regularly as the Guidant Management Committee. Generally, business communications at these meetings are informational in nature. Guidant Corporation's management is overseen by its Board of Directors.

As is the case for each of the Guidant Corporation businesses, Cardiac Rhythm Management (CRM) functions as an independent unit. It has its own officers who retain the authority for decision-making for operations and internal policy, with limited requirements for reporting to senior corporate management. CRM remains physically located at its site of origin, Saint Paul, Minnesota, while Guidant Corporation headquarters is located in Indianapolis, Indiana.

The products of the CRM business, pacemakers, implantable defibrillators, and their related lead systems, are used for their symptom-control and life-saving potential in high-risk patients.

2. SURVEILLANCE OF PRODUCTS IN THE FIELD

Postmarket surveillance of performance and reliability of implantable medical devices is a challenge for the entire industry, in part because of the absence of uniform performance standards, consistent surveillance methods and effective reporting requirements. The category of products manufactured by the CRM business have a limited advantage in regard to surveillance, because of the clinical requirement for continuous field follow-up of performance and battery reserve by physicians and field technicians. In addition, the CRM business requires that all employees report any complaints or information concerning malfunctions that come to his/her attention from any source. Despite this corporate requirement, there is no existing system that ensures return of explanted devices to investigate their functional status and integrity - whether after a natural death unrelated to device function, following normal battery depletion, or due to a device malfunction. This is a limitation that confronts the entire implantable cardiac device industry.

3. EVALUATION OF PRODUCT PERFORMANCE

Complaints about product performance and other concerns enter the CRM business of Guidant Corporation through its Technical Services system. Technical Services receives communications from a variety of sources, including physicians, health care facilities, CRM's field representatives, and direct patient contacts. The Technical Services group has personnel with diverse background, including engineers, a few nurses, but no physicians.

Incoming complaints are first evaluated by the Technical Services group. If an incident is considered to suggest device malfunction and/or to be clinically relevant, it is assigned to a Product Performance Engineer who has the responsibility to evaluate and classify the complaint, integrate the hardware findings generated by a reliability engineer, and consult with others as needed to determine the relevance of the problem. In parallel with this, and in compliance with an FDA mandate for assessment of individual events, it is determined whether a formal Medical Device Report (MDR) report is required, and if so submission of that report occurs within 30 days of receipt of the observation, unless there is an exemption.

A group with multiple areas of expertise, referred to as a Cross-Functional Team, may be assembled to coordinate this activity and work with the Product Performance Engineer to determine whether the nature and frequency of the complaint warrants the generation of a trend analysis to follow the product performance. The Cross-Functional Teams are constructed informally, and are

established or terminated on an *ad hoc* basis.

The trend analysis is begun, usually at the discretion of the Product Performance Engineer, when a complaint reaches a predetermined threshold of frequency or is interpreted to threaten patient safety. The usual standard to open a trend is the occurrence of four events of a kind during a 12-month period. However, a Product Performance Engineer may open a trend after as few as one event if there are safety concerns.

Once established, the trend is presented to and followed by the CRM Product Performance Committee until the trend is closed, at which point new events continue to be monitored by the Product Performance Engineer for an ill-defined period of time. A trend can be reopened if the Product Performance Engineer (or Product Performance Committee) determines that the frequency or nature of events has reached a previously designated threshold, which is not consistently defined in CRM policy.

Each trend initiates a formal Health Risk Assessment (HRA). The HRA is designed to categorize the event as to both its probability of occurrence and its severity. Physician participation in the HRA process is limited

If a question of patient safety is suggested or identified by the information generated, the trend may be referred to a series of other committees (Performance Evaluation Committee and Officer Escalation Group). The Officer Escalation Group has the authority to recommend to senior leadership of CRM whether an identified problem warrants advisories or recalls, and/or communication to physicians, patients, or the general public. The CRM President reviews these recommendations.

Prior to recent changes in Guidant Corporation methods (subsequent to the PRIZM 2 DR and RENEWAL 1/2 recalls and prior to this Report), senior management of Guidant Corporation was not involved in this process until it reached at least the level of the Officer Escalation Group, at which point CRM leadership decided whether to communicate information to the Guidant Management Committee. Involvement of Guidant Corporation executives usually did not occur until a CRM decision was made to issue a public announcement.

4. INTERNAL FLOW OF INFORMATION

The flow of information about product reliability within the CRM business and Guidant Corporation, and between these two fundamental levels of corporate structure, is impeded by the lack of clearly-defined reporting

procedures. When a specific problem escalates to a level at which a systematic problem is observed to be occurring at a frequency that exceeds pre-defined limits, or is thought to be life-threatening, channels of communication open, and information is communicated to higher levels of business and corporate leadership. However, in dealing with a new problem, for which frequency and clinical relevance have not reached a threshold for concern as defined in the HRA process, information is retained at lower levels, usually with no or only limited physician input. Thus, a trend may be established by a Product Performance Engineer and followed by the Product Performance Committee, or a closed trend monitored only by a Product Performance Engineer without any knowledge of the event at higher levels of CRM business or Guidant Corporation authority.

5. PUBLIC COMMUNICATION

CRM has established two criteria for communication of a reliability deviation of one of its products to physicians and patients:

a. "We act when predicted device performance does not achieve design or performance expectations."

or

b. "We act when we identify an opportunity to recommend to the clinical community a strategy for improved patient outcomes related to device function."

The panel interpreted these quoted statements to mean that: 1) the frequency of a problem must fail to achieve design or performance reliability expectations; and 2) the root cause has been identified and a mitigation that can be communicated to the clinical community has been devised. These requirements are driven by the perspectives of engineering, the company's commitment to continuous improvements, and FDA requirements. This is based upon long-standing CRM policies and procedures that place investigation, analysis, and recommendations to communicate device malfunctions or failures primarily in the hands of engineers. The input of physicians is limited, despite the company's stated concern for reliability deviations that can harm patients. There is no general policy governing how the company crafts an announcement of product reliability deviations. The process appears to be both complex and largely *ad hoc*. CRM business personnel, Guidant corporate officers, and a variety of external communications advisors participate in the process. There is no Guidant Corporation policy that defines what should be communicated and how and

when it should be presented, as reflected in the case of the announcements of device malfunctions during the spring and summer of 2005.

6. Genesis of Current Problems

In March of 2005, a death related to a low-frequency, but potentially dangerous defect in an implantable defibrillator product led to a stressed interaction between the external physicians involved in the patient's care and CRM representatives. The defect had originally been described, but not fully understood, and was believed to have been mitigated in April 2002, three years prior. It was subsequently determined that a second manufacturing change was required and a newly revised device was introduced in November 2002. The existing inventory of approximately 4,000 unmitigated devices continued to be implanted. This included 1,300 devices that were shipped from CRM's in-house inventory, and the remainder that were in possession of the CRM field sales force or in hospital inventories. CRM did not attempt to retrieve the unmitigated devices and the existence of the defect and subsequent manufacturing changes were not brought to the attention of physicians and patients because the communications criteria of CRM were not met. It was concluded by CRM that the risk of explant and replacement of older devices exceeded the risk of device failure.

At the center of the transparency issue was the long-standing restrictive external communication policy that resulted in physicians and patients feeling that they were not informed of relevant information about a potentially dangerous device malfunction, even after the first death occurred. After awareness of the problem came into the public domain via the news media, the consequences of the problem for Guidant were amplified by weak and conflict-ridden internal decision making processes used to respond to the issue. The combination of the product defect, a fatal event, and ineffective communication policies led to intense criticism of Guidant Corporation in the media. The public and physician reaction was magnified further by the subsequent announcement of a series of other low frequency defects in other devices, and FDA warnings and recalls. All of this was occurring against the backdrop of a highly publicized proposed purchase of the corporation.

7. Responses to Adverse News Reports

There is no structure within Guidant Corporation or the CRM business that provides a uniform hierarchal approach to public communication when the following circumstances emerge:

a. Adverse events that may threaten patient safety are observed but have not reached the pre-determined thresholds for consideration for public disclosure.

b. An adverse event enters the public domain and generates a negative reaction to the corporate image because of the way it had been handled prior to public disclosure.

c. There is a need to respond to adverse publicity with a uniform organized, and effective message.

To a large extent, responses emerge from the individual businesses, with no clear lines of authority between corporate level communications and those at the levels of the individual businesses. In the case at hand, conflicting approaches suggested by personnel in the individual businesses and by corporate communications personnel appear to have lead to friction between various levels of corporate structure and mixed messages entering the public domain.

8. Potential Consequences of the CRM Events of 2005 on Guidant Corporation

Guidant Corporation has determined that the greatest impact of the CRM events of 2005 was on the attitudes of physicians who are prescribers of the CRM products. A potential derivative of this effect is suggested in Guidant's recent financial reports, which demonstrate a decrease in 3rd quarter 2005 U. S. sales of its CRM products to $331.2 million from $469.0 million in the corresponding quarter of FY 2004, and a decrease in 4th quarter 2005 U. S. CRM sales to $341.2 million from $449.3 million in the corresponding quarter of FY 2004.

In addition, because the public views Guidant Corporation as a single entity, rather than a group of individual businesses, there exists the possibility that adverse reports from one business may have an effect on physician interactions with the other businesses, thus generating a more global influence on Guidant Corporation business.

9. Corporate Actions to Prevent Recurrent Problems

During the period of time that the Independent Panel was acquiring and analyzing information relevant to the issues defined by its Charter, Guidant Corporation had begun to make changes in Corporate and CRM business policies and procedures, intending to resolve some of its perceived problems in

a timely fashion. Its stated intent is to integrate the findings and recommendations of the Independent Panel into the matrix of changes made prior to the Panel's Report, seeking the best solutions to the problems identified.

10. Problem Resolution in Context

There is a general perception by the members of the Panel that virtually all of the problems identified in the scope of its mission are correctable by appropriate actions by Guidant Corporation and its CRM business. The function and reliability of products manufactured by the CRM business have made it a respected leader in its industry. However, the Panel has identified two fundamental principles that apply to CRM's current problems and are likely to govern the implantable device industry practices in the next decade:

a. Product quality alone is insufficient to protect and preserve business positions. The public demands greater transparency when product flaws are identified and mitigated.

b. A high priority must be placed on avoiding preventable deaths that may result from a low frequency product malfunction. A malfunction that is identified as potentially life-threatening should take priority over the overall malfunction incidence, even if the latter is better than design expectations.

The challenge to Guidant Corporation is to implement systems that will meet these expectations, and restore the Corporation's eminent status in the field of implantable pacemakers and defibrillators.

B. Overview of Major Recommendations

Based upon the findings and conclusions of the Independent Panel of Guidant Corporation, the details of which are provided below, the Independent Panel makes the following major recommendations:

1. Guidant Corporation is strongly advised to establish an external committee of experts to evaluate product performance and risk assessment data in order to advise the corporation regarding the management of information flow, and actions to be taken in regard to device failures and malfunctions. The committee should include expertise in cardiac electrophysiology, and other disciplines such as engineering, statistics, risk assessment, and patient advocacy/ethics. The committee should operate at arm's length from the corporation, its deliberations linked to the corporation by an ombudsman who will carry information between internal committees and the external group.

2. Guidant Corporation is advised to designate or hire an in-house physician whose primary responsibility will be patient safety and whose job description will include participation in product performance analysis, health hazard analysis, internal communications, and external communication policies and procedures.

3. Guidant Corporation is advised to strengthen management links between itself and its CRM business. This could be achieved by either a reconfigured version of the Officer Escalation Group of the CRM business, a redefinition of the role and activities of the Quality System Assurance Team (QSAT), or a newly formed committee, any of which would include membership of Guidant Corporation leadership as well as CRM business leadership. The purpose is to ensure adequate information flow and oversight between the parent corporation and the CRM business regarding postmarket product performance, patient safety issues, and communication policies.

4. Guidant Corporation is advised to enforce the general policy of the CRM business on the primacy of patient safety by better integrating patient safety concerns into the factual and statistical analysis of product performance and performance failures. The Independent Panel strongly believes that under no circumstances should a potential or manifest risk of a preventable death be superseded by statistical analyses that indicate that performance remains within the general guidelines of estimated failure rates from either the premarket estimates or postmarket experience.

5. Guidant Corporation is advised to ensure that its CRM business, and the Corporation generally, implement and enforce policies of transparency of information regarding product performance and health hazard risk to physicians and to the general public as new information is emerging. It is the opinion of the Independent Panel that a more aggressive transparency policy will achieve three goals:

   a. Discharge an implied obligation to physicians and patients

   b. Allow for better understanding of, and an appropriate response to, a significant new event by providing an appropriate context of the event

   c. Rebuild the trust and confidence in Guidant Corporation that was lost because of the dramatically increased flow of information that had not been shared prior to a major event.

6. Guidant Corporation, in general, and the CRM business in particular, should develop processes for more effective surveillance of marketed devices. This advice is given by the Independent Panel with the recognition that postmarket surveillance is a huge challenge that goes beyond the ability of Guidant Corporation, or any other business in the industry, to achieve alone. However, improvements can be made and should be sought.

7. Guidant Corporation is advised to re-visit the question of identifying a specific number of events that would serve as a trigger for initiating active notification of physicians about newly identified malfunctions or device failures. There was general agreement among the members of the Independent Panel that a *single event* that:

   a. Is associated with risk of death or serious injury,

   b. Has a suspected or defined basis for the malfunction or failure, and

   c. Is likely to be systematic and to occur in other patients,

   should be referred to the internal Guidant review body and the IRG for advice on active communications. In the absence of these qualifiers, a single event should *not* trigger active communication. However, such information should be made available passively in sources of information available to physicians, such as product performance reports.

   The next consideration had to do with the question of specifying a number greater than one, or a defined event rate, that would warrant such activity. The main concern was whether any minimum number should serve a threshold function, independent of other considerations. After considerable discussion, the Panel *rejected* the notion of setting a minimum number of

events or event rate because considerations of this type have to be evaluated in the context of the nature of the defect, anticipation whether it is likely to repeat, the anticipated or actual rate of accumulation, indications of whether malfunctions or failures are related to time from implantation, and the potential clinical consequences of any specific malfunction or failure. Accordingly, such determination should be made on a case-by-case basis, with two qualifiers:

a. Physician input regarding the question of potential clinical consequences must be an active part of the decision process; and

b. The decision process should be handled in a fashion that reflects true independence from commercial considerations.

Therefore, it is the recommendation of the Panel that these decisions should be made by the *Internal Oversight Body* recommended in **SECTION III.A**, with independent review and input from the proposed external *Independent Review Group* (IRG) (see **Recommendation 1**, above). In effect, the IRG would serve a function analogous to a data safety monitoring board of a clinical trial, relying upon the judgment of an informed independent scientific group, rather than a threshold of numbers, to drive decision-making recommendations about when to actively communicate.

In the case of an event for which unacceptable patient risk is self-evident from the information available, CRM/Guidant should act immediately, and subsequently inform the IRG as soon as possible.

8. When a life-threatening defect has been identified and mitigated in a specific product line, Guidant Corporation and its CRM business should expedite review by the internal Guidant review body and the external IRG. These groups should consider appropriate actions, including ceasing shipments of unmitigated devices, and retrieving those in possession of the sales force or in hospital inventories. When such unmitigated devices have been implanted, the company should inform hospitals, implanting physicians, and patients about the nature and projected incidence of the problem. The internal and external review groups should determine when and how such communications should take place.