September 15, 2005

Mr. W. Charles Becoat
District Director
Minnesota District Office
United States Food & Drug Administration
212 Third Avenue South
Minneapolis, MN 55401

Re: Guidant Cardiac Rhythm Management (CRM) 483 Inspectional Observations

Dear Mr. Becoat:

On September 1, 2005, FDA investigators Joseph Edwin, Kimberly Walker, and Norman Wong concluded an inspection of the St. Paul, Minnesota facility of Guidant Cardiac Rhythm Management ("Guidant CRM" or the "Company") by presenting us with observations on Form FDA-483. The information in and with this letter constitutes the Company's response to these observations.

First, let me assure you that these observations are receiving the full and complete attention of Guidant CRM. Members of our Management team with Executive Responsibility have been actively involved in assessing our Quality System in light of FDA's observations, and in the development of this response. Executive Management has commissioned a large team of individuals from throughout the Quality System, committed to supporting these improvement efforts. Additionally, an external quality system expert consultant has been engaged in this work ([***Redacted***]).

While we believe that our Quality System is in substantial compliance with the Quality System Regulations, we fully recognize the significance of FDA's inspectional observations and the important opportunity that they represent for continuous improvement. As such, we have taken a broad, thorough, and systemic approach to this response. This approach has and will continue to involve the inclusion of all Guidant

CRM sites (St. Paul Minnesota, Redmond Washington, Clonmel Ireland, and Dorado Puerto Rico) in both our assessment and corrective action plans. Further, our learning from these observations will be shared with other Guidant business units.

Second, our response addresses not only the specific observations and examples raised by the inspectors, but also foundational methodologies within our Quality System that have been identified through our assessment in preparation for this response.

Finally, our assessment has included a review of these observations in the context of product quality. As a result of that assessment, we would like to assure you that none of these observations impact the safety or effectiveness of Guidant CRM product.

Guidant's internal quality audits, as well as external quality system expert audits conducted during the coming year will verify the adequacy of the implementation of the commitments contained within this response.

In response to the specific INSIGNIA Pacemaker product trends cited in support of Observation #8, Guidant is acutely aware of the current challenge faced by the industry relative to decisions about when to communicate low-rate product performance issues. Guidant CRM has well-defined procedures that outline our process for considering such trends for physician communication. These procedures were followed with respect to the referenced INSIGNIA trends. However, we recognize the desire of the public to have even more information on product performance.

In response, Guidant CRM is making changes to its product labeling to better convey reliability expectations, including potential failure modes and expected performance levels. In addition, Guidant CRM Product Performance Reports will be distributed more frequently and include increased detail **[Redacted]**. Guidant also eagerly awaits the recommendations of industry panels and its own independent panel that are considering these vexing issues, and commits to consider further improvements to our process in light of their recommendations. In addition, Guidant CRM plans to issue a physician communication regarding the specific INSIGNIA product trends referenced by the inspectors, no later than September 30, 2005. We will work with FDA in advance of this communication.

Guidant CRM has a strong and visible commitment to quality system compliance and the continuous improvement of our Quality System. Our Quality Pledge, which all employees sign, on an annual basis during our Quality Week celebration in expression of their commitment to it, indicates our commitment to the outcomes of an effective quality system – products that are high in quality and reliability.

Our Quality Pledge states:

Quality is essential; lives depend on us. We pledge together to build the most reliable products and services. I work every day to drive Quality into everything that is Guidant.

Guidant's Code of Business Conduct makes the further explicit commitments to product quality and regulatory compliance:

Legal/compliance obligations - ***Guidant will comply with all applicable laws and regulations in all of its global operations. For everyone at Guidant, this means following the letter of the law and doing the right, ethical thing even when the right actions go beyond the requirements of the law. There are specific legal and regulatory requirements for many functional areas and business processes within Guidant, including, in particular, product development, finance, information systems, clinical studies and manufacturing functions, as well as internal controls, complaint handling and document control processes. You have an obligation to know and comply with those legal and regulatory requirements and company policies that impact your function. In many instances, the policies referenced in this Code go beyond the requirements of the law.***

Dedication to quality - ***Guidant's commitment to quality is measured by the consistent way its products provide therapy and save lives around the world every hour of every day. Everyone at Guidant must be dedicated to today's highest quality standards and commit to continuously improving them for tomorrow.***

This commitment has served us well over time, having as one result, the continuously increasing reliability of Guidant CRM products

Attached to this cover letter is a more detailed explanation of Guidant's actions in response to each individual observation in the FDA-483. Our response to each FDA observation includes the following components: (1) a summary of the corrective actions that the Company has taken or is taking; (2) a detailed discussion of the system-wide corrective actions relating to each observation; and (3) a detailed discussion of the more focused corrective actions that we have taken in response to FDA's specific observations. In many cases, because of the broad wording of the observation, we have also taken the opportunity to outline the extent of the existing quality system processes and procedures that are established in support of the relevant Quality System Regulation. We have also appended to this submission documentation supportive of our responses, including documentation that demonstrates the corrective actions that have been implemented. To the extent that we have indicated that corrective action has not been completed, we intend to supplement this response by providing additional information showing its completion.

[Redacted]

I would like to re-emphasize that we are committed to applying substantial resources to respond to FDA's observations and to implement further improvements. Furthermore, all of our employees, from our top executives to individuals on the production floor are aware of the efforts and personal commitments needed. We would appreciate the opportunity to meet with FDA to further discuss the matters addressed herein. We will be contacting you next week to determine a convenient time. In the meantime, should you require any assistance in reviewing this letter, or any of the attached documents, or require additional copies, please do not hesitate to contact us.

Sincerely,

[Redacted]
Vice President, Clinical & Regulatory Affairs
Guidant Cardiac Rhythm Management