United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

August 19, 2005

Via Electronic Transmission
Original via USPS Mail

The Honorable Lester M. Crawford, D.V.M., Ph.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Crawford:

The Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, among other matters. Accordingly, the Committee is responsible to the more than 80 million Americans who receive health care coverage under those programs, including payment for medical devices.

Thank you for providing my Committee staff with a briefing on August 18, 2005, regarding Guidant Corporation (Guidant) and its recall of the Ventak Prizm 2 DR Model 1861 (Model 1861). Pursuant to the Committee's ongoing inquiry into these matters, please provide the Committee with the following documents and information:

1. All Guidant analyses related to Model 1861 submitted to the Food and Drug Administration (FDA) since May 23, 2005, including but not limited to Guidant's risk assessment/analysis performed in 2002 and in 2005.

2. The total number of reported death(s) associated with Model 1861 as of August 18, 2005, as well as whether or not each death was device or non-device related.

3. The total number of adverse events associated with Model 1861 as of August 18, 2005, as well as whether or not each adverse event was device or non-device related.

4. A copy of the chronology that Mr. Timothy Ulatowksi referred to during the briefing with Committee staff.

5. A copy of the chronology related to Guidant recalls and/or other regulatory events that Dr. Daniel Schultz referred to during the briefing with Committee staff.

6. Identity of the FDA employee(s) assigned to Model 1861, from pre-market approval to its recent recall, and whether or not the same employee reviewed Guidant's annual postapproval reports related to Model 1861.

7. A copy of the current policies and procedures for the Center for Devices and Radiological Health related to communications between the FDA and manufacturers.

8. A copy of the most recent guidance document(s) related to reporting requirements under 21 CFR 814.39(a) and (b).

9. State whether or not the FDA has an agency-wide policy related to communications with manufacturers. Provide a listing of all relevant FDA regulations, policies and procedures that govern such communications. Specifically, identify all sections related to recording the substance of communications with manufacturers.

10. A status report on the development of guidance document(s) related to reporting requirements under 21 CFR 814.39(a) and (b), including a detailed timeline of dates related to the development, issuance, and revisions of prior or existing guidance document(s).

11. A copy of all documents submitted by Guidant to the FDA since May 23, 2005, including but not limited to all regulatory submissions and analyses related to recalled models, other than Model 1861.

12. Provide a chart of all device changes submitted by Guidant since May 23, 2005, including but not limited to changes reported in accordance with 21 CFR 814.39(a) and (b). Please provide the information in the following chart, including whether or not the submission resulted from Guidant reconsidering its reporting requirements under 21 CFR 814.39(a) and (b):

Date Submitted	Date of Device Change	Model(s) No.	Description of Change	Reporting Requirement Reconsidered

Thank you in advance for having your staff coordinate with my staff about this letter by August 24, 2005. Please provide the information and documents related to requests 1-8 by August 26th, and 9-12 by September 7th, unless they are available sooner. Any questions or concerns should be directed to

All formal correspondence should be sent via facsimile to (202) 228-2131. All original material should be sent via USPS mail. Please do not hesitate to contact me if you have any concerns.

Sincerely,

Chuck Grassley

Charles E. Grassley
Chairman