DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
212 3rd Ave. South Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134	12/15/2005 - 02/09/2006* FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dale W. DeVries, Vice President of Clinicals and Regulatory Affairs

FIRM NAME	STREET ADDRESS
Guidant Corporation	4100 Hamline Avenue North
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
St. Paul , MN 55112	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Not all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems have been identified.

Specifically, An analog to digital latching fault has been identified in Prizm I, Prizm II and Vitality pulse generators that can result in a loss of tachy therapy. There have been four confirmed and two unconfirmed field events since 5/13/2002 for this cause. A software fix was developed by 5/6/2004 (SCR #1883) to correct this fault in the Renewal RF design project. However, a fix was not submitted to FDA for certain affected preexisting devices until August, 2005.

Annotation: Promised to correct.

*** DATES OF INSPECTION:**
12/15/2005(Thu), 12/19/2005(Mon), 12/20/2005(Tue), 12/21/2005(Wed), 12/22/2005(Thu), 01/03/2006(Tue), 01/04/2006(Wed), 01/05/2006(Thu), 01/06/2006(Fri), 01/10/2006(Tue), 01/11/2006(Wed), 01/13/2006(Fri), 01/17/2006(Tue), 01/18/2006(Wed), 01/25/2006(Wed), 01/26/2006(Thu), 01/27/2006(Fri), 01/30/2006(Mon), 01/31/2006(Tue), 02/01/2006(Wed), 02/09/2006(Thu)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Alison A Stone
~~Alison A Stone~~, Investigator

Ralph W Jerndal
Ralph W. Jerndal, Investigator

Alison A Stone

SEE REVERSE OF THIS PAGE	This is a modified document.	DATE ISSUED 02/09/2006