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	08/22/2005 - 09/01/2005
	FEI NUMBER 2124215

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: R. Frederick McCoy Jr., President CRM

FIRM NAME	STREET ADDRESS
Guidant Corporation	4100 Hamline Ave N
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Paul, MN 55112-5798	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

Procedures for conducting quality audits were not complete.

Specifically,

The CRM Audit Procedure 005014 requires preparation of an Audit Plan and checklist. Review of 2005 CAPA Audit Plan noted a lack of specific details to ensure complete coverage and that all the QSR requirements are met. There was no detailed reference to the auditing of non-conforming data sources or the analysis of those non-conforming data sources.

OBSERVATION 2

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

Specifically,

- Root cause has not been determined for TR 05013 Rev. B 06/22/05 INSIGNIA . Subject matters for the trend report contains the Hazard Description "The device goes to no output and fails to deliver therapy."
- There are no corrective and preventive actions to design control inputs/process procedures specifically addressing processes required to develop product and/or product hybrids to mitigate or reduce SEU (single event upsets) for circuits using technology.
- There are no corrective and preventive actions to change design control

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procedures to identify or prevent memory overflow or similar software programming problems from recurring.

OBSERVATION 3

Procedures were not complete and implemented for monitoring and control of process parameters for validated processes.

Specifically, the process was validated using for acceptance testing.

Specifications for the output of the process and acceptance criteria are in terms of has not been used on the Brady hybrid assembly line for acceptance since April 2005. It has been replaced by process. The process cannot determine process is in compliance with requirements. There is no other process control method used to sample and test to ensure specification for the is met.

OBSERVATION 4

A process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures.

Specifically,

- equipment, when used for process screening following on the Tachy and Brady hybrid assembly lines, has not been validated.
- used on the Tachy hybrid assembly line following the process has not been fully validated. The operational qualification did not include testing the equipment with reference hybrids mounted with non conforming components. The PQ part of the process validation has not been conducted.
- In addition to the above, process validation has not been performed for any inspection processes on the Brady or Tachy hybrid assembly line using processes.

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OBSERVATION 5

Procedures to ensure that equipment is routinely maintained were not established.

Specifically, the maintenance and calibration procedure for equipment does not require verification with the special standard, to ensure that the acceptance and rejection criteria for the are being met.

OBSERVATION 6

During production, component and device characteristics are not fully monitored and controlled.

Specifically, acceptance inspection following the on the Brady hybrid assembly line was removed. The volume characteristics of the process cannot be inspected and controlled using method.

OBSERVATION 7

Procedures for changes to methods were not complete.

- was taken off line in the Brady hybrid manufacturing process and replaced with process for following processes. There was no approved process change order for the removal of om the Brady hybrid assembly line.
- During the walk through of the Brady hybrid assembly line, a number of process control charts, ie. " with criteria for stopping production for process adjustments were observed throughout the processing floor. These production limits have been set without process verification and validation activities to ensure finished products are meeting finished specification requirements.

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OBSERVATION 8

Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.

Specifically,

- The Insignia product has been identified with potential no output and fails to deliver therapy with failure in Refer to TR 05013 Rev. B 06/22/05 INSIGNIA The failure was first confirmed in an analysis with a 11-14-2003 start date and the last of approximately failures was confirmed with a start date of 7-11-2005. The root cause for TR05013 has not been identified. The products continue to be distributed and users have not been informed of a potential no output failure mode.

- Users have not been informed of the potential for the Insignia pacemaker to fail in a no output failure mode due to identified in TR 03030. There have been approximately devices that have been explanted where returned failure analysis confirmed the failure was due to The most recent failure and explant of a device for this problem occurred in July 2005.

OBSERVATION 9

Software used as part of production and the quality system has not been fully validated for its intended use according to an established protocol. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, the software used to capture the RPR (Return Product Report) data which includes return device tracking, failure analysis information, and failure analysis results has not been verified or validated in regards to missing RPR records. There are missing records for which the firm cannot account for the details of the contents of the deleted record, who deleted the record, or why was the record deleted. The RPR records are part of a full e-records system. There are no hardcopy records of the deleted records.

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OBSERVATION 10

Appropriate sources of quality data are not adequately analyzed to identify existing and potential causes of nonconforming product and other quality problems.

- Failure data collected with each equipment following are not routinely collected and analyzed as a process monitoring and control on the identifies non-conformance as to the
- used on the Tachy hybrid assembly line at is not routinely analyzed to identify existing and potential causes of nonconforming product and other quality problems. equipment will capture and maintain non-conforming product images. These images are not routinely analyzed for quality non-conformances from defects occurring from the component mounting equipment.

OBSERVATION 11

Processes have not been approved. Electronic records are used, but they do not meet employee accountability/responsibility policy and signature manifestation requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, the removal of from the Brady hybrid assembly line in April 2005 did not have a documented process change order with implementation date, approval signature, and approval date.

OBSERVATION 12

The document control procedures do not designate an individual to review documents for adequacy and approve them prior to issuance. Electronic records are used, but they do not meet signature manifestation requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, the work order used to remove from the Brady hybrid assembly line in April 2005 does not contain a date and approval signature.

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OBSERVATION 13

Rework and reevaluation activities have not been documented in the device history record.

Specifically, occuring after are not considered to be reworks and are not captured in device history documents.

OBSERVATION 14

Document control procedures were not complete. Electronic records are used, but they do not meet retention requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically,

- Gaps are encountered in the RPR record numbers where sequential auto record numbering is used to create the RPR record numbers.
- Work orders are generated and implemented without evidence of electronic signature or other evidence of signature and approval date.

OBSERVATION 15

The device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Specifically,

- Device history record (Traveler #12802069 started 07-Oct-2002) for the fails to document the performance of an acceptance inspection, whether the inspection was or product passed or failed the acceptance inspection, and if the product had been reworked and/or the times the product had been reworked.
- Device history record (Traveler #19686977 started 23-Apr-2004) for the fails to document the performance of an acceptance inspection, whether the inspection was or product passed or failed the acceptance inspection, and if the product had been reworked and/or the times the product had been reworked.

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FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

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