DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
466 Fernandez Juncos Ave. San Juan, PR 00901-3223 (787)-474-9500 Fax:(787) 729-6809 Industry Information: www.fda.gov/oc/industry	09/17/2012 - 10/02/2012* FEI NUMBER 3006705815

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Angel L. Ortiz Rivera, General Manager

FIRM NAME	STREET ADDRESS
St. Jude Medical Puerto Rico LLC	Lot A Interior -Carr #2 Km 67.5 Santana Indl. Park, Sector Los Pinos
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Arecibo, PR 00613-6025	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 receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

Procedure #602727, Product Experience Report Handling, PR LLC, established on site to define the instructions for handling and trending manufacturing related complaints from products manufactured in Puerto Rico and to provide instructions for reporting results to the appropriate SJM Division fails to require complete documentation of activities conducted to ensure a timely investigation (when does the (b) (4) for local investigations start) or describe data analysis conducted as part of complaint trending. Section 7.3, Data Analysis, fails to include the scope and actions associated to the analysis of data as no information is included with the procedure on: how the analysis is conducted and reported to the site for evaluation and action; elements to be evaluated at the site with the reports provided or at least minimum information to be included during the local evaluation of data provided by the Division; scope (period of data reported) of the analysis and source of data reported to justify reported combined defects/product families in order to accurately determine trends (if any).

OBSERVATION 2

Procedures for identifying product during all stages of receipt, production, distribution, and installation have not been adequately established.

Specifically,

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1. The use of the software tool '(b) (4) implemented on site as reported by local managers in February 2012 and observed in place in the manufacturing/assembly clean room- specifically in the product inspection stations for HV and CRT Leads- has not been fully documented to support the firm's claim of no impact on production operations for the assembly of leads. Documents issued for the(b) (4) observed in place and in use on the manufacturing clean room were not available nor provided during this inspection or any other documented evaluation to support the firm's claim of reported use "(b) (4) ". The instruction to scan the bar code label on each lead prior to final inspection activities (for(b) (4)) is not part of any production record (traveler) or manufacturing operation available on site.

2. Procedure #603348, Material Handling Control, PR LLC, established on site to assure the effectiveness of material handling controls in place for the manufacture of leads, pacers and ICD's fails to ensure adequate documentation of line clearance activities. Line clearance activities executed as described in the procedure and documented with form #101851, Material Handling Control (MHC) Checklist, does not require documentation of the date when the line clearance (verification of work station to reduce or eliminate the possibility of incorrect materials) was conducted or when the activity was reviewed-there is no documented evidence to ensure that in fact the activity was conducted **prior** to initiation of assembly activities as reported on the checklist.

The following deviations were noted during review of protocols and activities (reported by site managers) conducted to support PMA P810002/S080/A001.

OBSERVATION 3

Process validation activities and results have not been approved and adequately documented.

Specifically,

Activities conducted on site describing the performance qualification report for the (b) (4) (b) (4) of(b) (4) (b) (4) executed as described on protocol #90084631, 12/2011, and reported as successful on protocol report #90087565, January 2012, failed to include full documentation of activities conducted as executed including:

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a. Full description of product samples reportedly manufactured at Woodridge, MN, and Caguas, PR, for the exercise in order to demonstrate that actual product used during the validation exercise is equivalent/similar to (b) (4) (justification for use, accurate size /material description, comparison of " native units"/ "demo units"/ "clinical units"/ "PCD" or "product challenge devices" vs. actual product units). Differences between packaging presentations described as "shipping crates", "shipping cartons", and "shipping boxes" were not documented and were used interchangeably throughout the written protocol to describe different/same product presentations.
b. Documented evidence to support the lack of product functional testing reported. The protocol reports that functional tests would not be required solely because the cycle under validation at Arecibo ((b) (4)) is "the same" as the cycle conducted by the external contractor located at Minnesota-US. Impact on the product and seal integrity was not documented of different environmental conditions (including shipping) from product manufactured-shipped to Minnesota/Caguas and (b) (4) in Puerto Rico.

OBSERVATION 4

Device packaging and/or shipping containers are not designed and constructed to protect the device from alteration or damage during processing, storage, handling, and distribution.

Specifically,

Protocol #90088394 approved on site on July 2012 for the Packaging Integrity Performance Qualification of (b) (4) Products (b) (4) at Arecibo Site, and executed to provide documented evidence to demonstrate that the packaging tray integrity of (b) (4) units is maintained after a (b) (4) (b) (4) , fails to report impact on product manufactured at Woodridge, Minnesota-US and (b) (4) at Arecibo, Puerto Rico or justification for lack-of . The protocol includes only tests conducted on product manufactured at Caguas (PR) transferred to Arecibo (PR)- but fails to include tests on product manufactured at Woodridge and shipped to Arecibo (as proposed on PMA P810002/S080) or documented evidence to support the lack of such tests.

In addition, protocol # 90088394 reports that functional tests on product is not required because it was completed under protocol #873526(January 2008), which only includes tests on product manufactured at Caguas (PR) and (b) (4) at Minnesota. No documented evidence is included with either protocol to support the firm's conclusion of no impact on the product and seal integrity under different environmental conditions (including shipping) for the new proposed (b) (4) site vs. the two

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proposed manufacturing sites.

OBSERVATION 5

Software validation activities and results for computers or automated data processing systems used as part of production have not been adequately documented.

Specifically,

Not all activities reported on the (b) (4) #60025082,Rev A., including test requirements/ design/ procedures and acceptance criteria for the verification of the (b) (4) used to control the (b) (4)) (b) (4) cycle, were fully documented to comply with the requirements described on the plan. For example, section 8.4 of the (b) (approved on June 2009) includes the CFR 21 Part 11 Compliance and System Security requirements,describing procedures and levels of access to be granted for users accessing the controller. However, no formal procedure was established on site for the implementation of the system security requirements prior or during the execution of the protocol to control users with access to the system. Furthermore, no documented evidence was included with the execution of the plan to confirm that compliance with the system security was in fact executed.

OBSERVATION 6

Procedures for product handling have not been adequately established.

Specifically,

Procedure # 90097987, (b) (4) , including instructions for the preparation for shipment to Arecibo of (b) -(b) (4) units and handling during (b) (4) and (b) (4) (which included activities executed for protocol #90084631, 12/2011, and report #90087565) fails to include an accurate depiction of units used for shipping materials and accurate depiction of responsibilities per areas involved ("trained inspectors" vs. "shipping") in the process of handling units shipped to Arecibo for (b) (4) and subsequent shipment to another site for further processing, after (b) (4)

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Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Promised to correct.

*** DATES OF INSPECTION:**
09/17/2012(Mon), 09/18/2012(Tue), 09/19/2012(Wed), 09/20/2012(Thu), 09/21/2012(Fri), 09/24/2012(Mon), 09/25/2012(Tue), 09/26/2012(Wed), 09/27/2012(Thu), 10/02/2012(Tue)

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