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December 7, 2012

Alonza E. Cruse
Los Angeles Office District Director
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Re: St. Jude Medical IESD Update Report to FDA-483 Responses

Dear Mr. Cruse,

St. Jude Medical Implantable Electronic Systems Division, Sylmar, CA (hereafter referred to as "St. Jude Medical IESD-Sylmar") is providing an update to our previous responses provided to FDA on November 7, 2012 to the FDA-483 inspectional observations. The FDA-483 had been issued to the St. Jude Medical IESD-Sylmar by the FDA investigator on October 17, 2012.

In our November 7, 2012 response to the FDA-483 inspectional observations, there were a number of identified actions that were in progress. The purpose of this correspondence is to provide FDA with an updated status of the actions that were still on-going as of the date of our previous response.

We consider the information contained in this letter and its attachments as confidential commercial information and not subject to disclosure under the Freedom of Information Act. Accordingly, we have designated this letter and its attachments as confidential.

Please contact this office should you require any assistance in reviewing this letter, or any of the attached documents.

Sincerely,

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In St. Jude Medical IESD-Sylmar's response to the FDA-483 Inspectional Observations received on October 17, 2012, we had identified a number of actions that were in progress. The purpose of this correspondence is to provide FDA with a status of the actions that were in progress as of the date of our November 7, 2012 initial response.

Table 1 summarizes the eleven observations and identifies the observations for which a status update is being provided.

Table 1 Summary of 11 FDA-483 observations and action status

Observation Number	Action Status
1	Process Validation Gap Analysis and Plan to install pressure and flow meters provided in this monthly update.
2	Test Method Validation Plan and associated procedural changes and training provided in this monthly update.
3	No planned actions completed as of this monthly update per Nov. 7, 2012 commitments. Revisions to FMEAs are underway with an update to the (b) (4) (b) (4) leads FMEA expected by Jan. 31, 2013.
4	Plan to review Design Changes and Process Changes provided in this monthly update.
5	No planned actions completed as of this monthly update per Nov. 7, 2012 commitments. Updates to the design control procedure have been completed as a response to Observation 2C and 2D. A review of currently manufactured products to assess if the associated Design History Files require remediation is underway and progress updates will be provided in the next monthly status report.
6	Training of internal auditors completed and plan to develop design control training module provided in this monthly update.
7	Plan to retrospectively review CAPAs and verification of effectiveness developed and provided in this monthly update. A plan to develop a consolidated hazard list with severity assignments across product lines has also been initiated.
8	No planned actions completed as of this monthly update per Nov. 7, 2012 commitments. Revisions to the CAPA procedure to specify data trending from specific sources of non-conformances are underway and expected to be completed by Dec. 31, 2012. Review of CAPAs from Oct. 2010 to Oct. 2012 to assess and document that actions did not adversely affect the finished product are also underway and expected to be completed by Dec. 31, 2012.
9	Actions completed as of Nov. 7, 2012 response.
10	No planned actions completed as of this monthly update per Nov. 7, 2012 commitments. Review of CAPAs from Oct. 2010 to Oct. 2012 to add a Page File Index is underway and expected to be completed by Dec. 31, 2012.
11	Plan to implement a Preliminary Out of Tolerance Alert for Inspection, Measuring, and Test Equipment developed and provided in this monthly update.

Observation 1 – Process Validation

Action	Status
(1a, b) Conduct a gap analysis between the updated procedure "Process Validation" SOP4.2.1, Rev. U and the validation documentation associated with the equipment for the (b) (4) machines to identify gaps. Plan and take action to close any identified gaps.	Gap Analysis was completed Nov. 30, 2012. Four gaps identified; none were determined to result in an unacceptable condition. See Attachment 1-1
(1f) Provide a plan with completion dates for installation and subsequent training regarding installation of pressure and flow meters for the (b) (4) on the (b) (4) machines.	Plan with completion dates for installation of pressure and flow meters was completed Dec. 6, 2012. We will update FDA once the installation is completed. See Attachment 1-2

Observation 2 – Design Verification

Action	Status
(2A) Test Method Validation procedure release and training of users	Provided the procedure in Nov. 7, 2012 response and completed training on Nov. 28, 2012. See Attachment 2-1
(2A) Develop inventory of test methods used during development of Durata.	Completed Nov. 30, 2012. See Attachment 2-2
(2A) Determine if each Durata test method requires validation per revised procedure.	As of Nov. 30, 2012, we identified (b) tests requiring validation. This includes verifying that standards based tests are being run in a repeatable manner, reviewing validation of tests run by outside labs, and reviewing some testing performed on non-critical product attributes such as dimensions. We will update FDA on status of the validation. See Attachment 2-2
(2A) Develop plan to address test method validation for other product lines.	Completed Nov. 30, 2012. See Attachment 2-3
(2A.a) Validation of the test method for the (b) (4) Test Specification of (b) (4) has been initiated.	The (b) (4) test has been reviewed and the test method validation protocol is being drafted. (Expected completion: Apr 30, 2013)
(2A.b, 2A.b.i) Validation of the (b) (4) (b) (4) test method has been initiated.	The (b) (4) test has been reviewed and the test method validation protocol is being drafted. (Expected completion: May 31, 2013)
(2A.c) Review the (b) (4) test method to determine extent of validation activities required per Test	Three tests identified, with two requiring further validation. The test method

Method Validation procedure. We are reviewing the test method to determine extent of validation activities required per SOP 60041416 *"Test Method Validation"*, Rev A. If required, we will validate according to the result of the assessment.	validation protocol is being drafted. See Attachment 2-4 Tests will be run when the test method validation has been completed.
(2C and 2D) Revise design control procedure to require design verification items to be completed prior to design validation using gate phase review process. Train personnel. Remediation activities shall include a systematic review of design history files for products currently manufactured and distributed in the US. Gaps identified will be prioritized and subject to remediation. (Expected completion: Jun 30, 2013)	Revised and released the Global Product Development Procedure SOP2.1, Rev. T, Sec. 8.8 and 8.9; training was completed on Nov. 29, 2012. See Attachment 2-5 and 2-6

Observation 4 – Design Change

Action	Status
(4) Develop plan to retrospectively review documents for Design Changes and Process Changes and assess any impact/validity of associated verification.	Sampling plan Doc. 60047117 Rev. A developed on Nov. 30, 2012 to determine applicability of "Corrective Action" vs. "Design or Process Change". Report to be completed by Feb. 28, 2013. See Attachment 4-1

Observation 6 - Training

Action	Status
(6A) Procedures that comprise the design development activities will be further improved to ensure that approval of the phases of development is clearly required and documented. Revise Internal Audit procedure and train internal audit team on design procedures, emphasizing requirement to examine documents for required approvals and any changes to design inputs.	Revised and released the Global Product Development Procedure SOP2.1, Rev. T, Sec. 4.5.2; training was completed on Nov. 30, 2012. See Attachment 2-5 and 2-6. Revised the Internal Audit procedure SOP4.1.2 Rev. AE, Sec. 5.4 and developed the Audit Checklist Guidelines (Doc. 60047019 Rev. A). Training was completed on Nov. 30, 2012. See Attachment 6-1, 6-2, and 6-3.

(6B) Develop training plan for personnel performing and documenting design control activities.	Plan was completed on Nov. 30, 2012. Plan outside training from (b) (4) followed by additional procedural changes and development of training module. Expected completion April 30, 2013. See Attachment 6-4.

Observation 7 – CAPA System

Action	Status
(7A.a, 7A.c) Develop plan to retrospectively review CAPAs and identify any potential gaps in verification of effectiveness (VOE) activities.	Developed a protocol on Nov. 12, 2012 to retrospectively review two years worth of CAPAs. We will update FDA on status of the VOE review. See Attachment 7-1
(7A.b) Due to the implementation date of the inspection criteria clarification in Sept 2012 for PIR 12-007, the additional check will be completed after receipt of at least n=(b) (4) of the vendor supplied component.	This level of component receipts is expected by (b) (4)
(7A.d) An index, form number 60046468, Revision A will be added to CAPA files not already remediated which were opened between Oct 31, 2010 and Oct 31, 2012. The index will specify the contents required and added to each CAPA file.	A file index will be added to these CAPA files opened within this time period by Dec. 31, 2012.
(7B) We will enhance our Failure Mode Effects and Analysis (FMEA) across all product families. A team comprised of Quality, Clinical, and Development personnel will review existing severity assignments for appropriateness, and also assign probabilities based on empirical field data.	A plan to develop a consolidated hazard list with severity assignments across product lines has been initiated. This will form the basis for enhancing the current FMEAs. A review of the high voltage leads hazards, severities, and probabilities is in progress and we expect to have the (b) (4) leads FMEA updated by Jan. 31, 2013.

Observation 11 – Inspection, Measuring & Test Equipment

Action	Status
(11) Develop plan to implement a Preliminary Out of Tolerance Alert for calibration of equipment.	Plan developed on Nov. 30, 2012 to require calibration of test equipment if measurements exceed (b) of the tolerance range. Identify and update documentation by Feb. 28, 2013, followed by procedural revisions and training by March 31, 2013. See Attachment 11-1