DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food and Drug Administration 19701 Fairchild Irvine, CA 92612-2506 949-608-2900 Industry Information: www.fda.gov/oc/industry	09/25-10/17/2012
	FEI NUMBER 2017865

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric Fain, President

FIRM NAME	STREET ADDRESS
St. Jude Medical IESD	15900 Valley View Court
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sylmar, CA 91342	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 (I) (WE) OBSERVED:

1. Process Validation

Your process validation protocol covering (b) (4) different machines performing (b) (4) of (b) (4) and (b) (4) was inadequate in that:

a. the protocol covers (b) (4) machines installed from 1999-2011 and does not evaluate the potential differences in the machines.

b. you create multiple different holders to hold the leads during (b) (4) and did not specify how you would install and verify the holders as part of the validation.

c. Your statistical rationale for your sample size for your "parametric method" sample size selection is unclear

d. you specify 95% of the population shall exceed specifications as your predetermined acceptance criteria.

e. in your process validation o (b) (4) was unable to verify the results of your 3 cross-sectioned samples

f. you do not measure the pressure and flow of the (b) (4) that is delivered to you (b) (4) at the end points of use, which specifies a maximum of (b) (4) and a (b) (4) per (b) (4) recommended consumption flow

Annotation: Promise to correct.

2. Design Verification:

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A. Your design verification activities were inadequate in that you failed to validate 3 test methods you created in-house to verify your design inputs during your design verification, for example:

a. Durata input specified for verification testing: (b) (4) of the (b) (4) ip shall be (b) (4) per (b) (4) Non-validated test method: (b) (4)

b. Durata design input specified for verification testing: (b) (4) shall not change by more than (b) (4) %. Non-validated test method (b) (4) test.

b(i). You are currently conducting design verification testing using th (b) (4) test method testing (b) (4) (b) (4) leads (model number# (b) (4) and IDE# (b) (4) (b) (4) model (b) (4) and model # (b) (4).

c. Durata design input specified for verification testing: (2 items tested) in (b) (4) condition shall be maximum (b) (4) (b) (4) an (b) (4) condition minimum of (b) (4) (b) (4) Non-validated test method: (b) (4)

B. You failed to follow your written test procedure during design verification testing of your (b) (4) test, which ensures th (b) (4) s not greater tha (b) (b) to prevent a potential (b) (4) Your procedures require each lead to be tested 5 times and the mean of the 5 tests is considered your test result. During your design verification you only tested each lead one time to determine your design verification results as apposed to determining the mean of 5 tests results per lead.

C. You conducted your Durata (b) (4) esign verification to verify the "(b) (4) (b) (4)" on 06/07/07 which was prior to your approval of your Durata lead inputs revision #004, Document number 60010874 which occurred on 07/16/07.

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D. Your (b) (4) design verification activity to verify the design input of "(b) (4) (b) (4) " was conducted on 06/07/07 which was after you implanted (b leads into canines as part of your design validation.

Annotation: Promise to correct.

3. Design Validation:

A. Your Durata risk analyses (2007) identified canine testing as a mitigation addressing (b) (4) (b) (4) . In the mitigation you reference study (b) (4) as your design verification and it was inadequate in that:

a. It did not include predetermined acceptance criteria corresponding to (b) (4)

b. A review of your approval of the verification found 4 of the total population of 30 canines implanted to support a samples size of 21 canines tested had (b) (4) (b) (4)

c. you failed to evaluate one of the study results which stated, (b) (4) (b) (4)

B. Your Durata design risk analysis ((b) (4)) is inadequate in that it combines different recalled and not recalled devices, for example:

a. Your "(b) (4) out for all (b) (4) leads states a severity of (b) (4) and a probability of (b) when your design team stated the Durata design decreased the risk of this (b) (4) root cause.

b. Your "(b) (4) " for al (b) (4) leads states a severity of (b) (4) nd a probability of (b) (4) hen your design team stated the Durata design decreased the risk of this (b) (4) root cause.

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4. Design Change:

(b) (4) Design Change:
You documented (b) (4) of (b) (4) levices failed your "(b) (4) test" predetermined acceptance criteria of "(b) (4) %" during your design verification testing. You then changed your (b) (4) (b) (4) in the (b) (4) from (b) (4) to (b) (4) inches, produced and tested (b) (4) ewly manufactured (b) (4) (b) (4) leads and approved your design verification without determining the validity of any of your other design verification activities that were conducted using the (b) (4) eads manufactured under previously approved specifications (design inputs).

Annotation: Promise to correct.

5. Design History File:
Your firm was unable to clearly identify the full content of your Durata design history file, for example:
I was unable to determine when your firm approved your Durata design inputs, outputs, verification, validation, design transfer and when you conducted your final approval of your Durata design. I was also unable to determine which inputs were changed or unchanged from 1997 onward which is the origination of your Durata design.

Annotation: Promise to correct.

6. Training:

A. Internal Auditor Training:
Your training of your internal auditors is inadequate in that your audit team audited the Durata design project in January of 2012 when after 6 days of inspectional requests of your firm to provide the Durata design history file I was unable to determine when your firm approved your Durata design inputs, outputs, verification, validation,

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design transfer and when you conducted your final approval of your Durata design. I was also unable to determine which inputs were changed or unchanged from 1997 onward which is the origination of your Durata design.

B. Design Training:
You have inadequate training of design controls, for example:
a. After 6 days of inspectional requests I was unable to determine which design inputs were changed or unchanged from 1997 to present day.
b. 4 personnel approved your design validation study with an ambiguous input

Annotation: Promise to correct.

7. CAPA system:

A. Your CAPA system is inadequate in that in reviewing 11 of your recently closed CAPAs I found:

a. two were closed and did not state a verification of the effectiveness would be performed.

b. two were closed and stated "no effectiveness check is required" with no justification, which is required by your procedures if no verification check is performed.

c. six of the CAPAs are closed and state an effectiveness check is going to be done in 6-9 months. None of the 11 CAPAs reviewed, including these 6, specify how you are going to verify your effectiveness.

d. PIR10-007 was closed on 03/25/2011 and an employee documented that the CAPA was not effective on 10/20/2011 and the problem of (b) (4) in your lead continued, implemented two actions to correct the original problem and requested a new effectiveness check be performed at a later date. This CAPA was not re-opened nor was there a separate CAPA opened after the original CAPA action taken was determined to be ineffective. There is no document control dictating which documents are part of or not part of this CAPA.

e. You failed to re-evaluate and update your risk analysis for CAPA PIR 10-007 when the mitigation identified in

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the risk analysis failed and you continued to have the problem of (b) (4) (b) (4) nd then implemented further actions to solve the problem

B. Your Corrective Action #PIR-10-005 for your Riata lead was inadequate in that you failed to evaluate the validity of some of your Durata lead design verification and validation activities.

Annotation: Promise to correct.

8. CAPA Procedures:
Your CAPA procedures are inadequate in that they do not address:

1. Determining whether the action taken adversely affects the finished device,

2. Identify data sources you are going to analyze; such as complaints and MDRs.

3. verifying or validating the effectiveness of a CAPA

And the procedures state you will determine the effectiveness of the CAPA after the CAPA is closed

Annotation: Promise to correct.

9. Complaint Files:

Your complaint handling procedures are inadequate in that:

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a. Your procedures do not dictate that you will make a decision as to whether an investigation is necessary.

b. A review of your Durata Model 7121 SN AHD32782 complaint found:
1. you did not specify whether an investigation was necessary
2. Your decision of whether this complaint was a medical device reportable event was conflicting in that you stated "not implanted" as a justification for the non-reportable event when the lead was implanted and then removed during the implant procedure.

Annotation: Promise to correct.

10. Document Control:
Your document control is inadequate in that while reviewing:
a. CAPA#PIR 10-005 I was unable to determine which document were included in the CAPA and which were not, for example the attachment pages are not identified as being associated with the CAPA and a separate "knowledge transfer to future HV lead designs" memorandum was not identified as being part of your CAPA.

b. Durata Model 7121 SN AHD32782 complaint I was unable to determine which documents were included in the complaint as the documents are not identified as being linked to the complaint and there is no individual complaint identifier.

Annotation: Promise to correct.

11. Control of Inspection, Measuring, and Test Equipment

Your calibration procedure and implementation is inadequate in that your procedures dictate calibration and you are performing verification, unless it falls out of your tolerances upon which you calibrate the equipment; for example:

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a. You failed to follow your procedures which require you to calibrate th(b) (4) in(b) (4) of your (b) (4) used to(b) (4) leads. In actuality you(b) (4)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."