**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 2/7/2017-2/17/2017*<br>FEI NUMBER<br>2017865 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Vishnu Charan , VP Operations

| FIRM NAME | STREET ADDRESS |
|---|---|
| St Jude Medical Inc. | 15900 Valley View Ct |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Sylmar, CA 91342-3577 | Class III 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 corrective and preventive action have not been adequately established.

Specifically,

a. A review of 42 Product Analysis Reports produced between 2011 and 2014 showed that the firm repeatedly concluded that the cause of premature depletion of the Greatbatch QHR2850 battery could not be determined in instances when the analysis provided ample evidence that lithium cluster bridging had prematurely drained the battery.

b. Failure investigations were not timely. A timeline provided by the firm stated that St Jude Medical was in discussion with Greatbatch about redesign of the header insulation area in January, 2013. Greatbatch proposal (b) (4) documents that this redesign project was formally initiated on 3/1/2013. However, CAPA # 13-017 for the premature battery depletion issue was not initiated until the following December, and Risk Analysis (b) (4) was not completed until 4/9/2014.

c. The firm did not follow their CAPA procedures at the appropriate time as defined in SJM Corrective and Preventive Action (CAPA) SOP ((b) (4) Rev D) and the SJM Corrective and Preventive Action WI ((b) (4) Rev C) when responding to the MedSec report released on August 25, 2016. For example, the firm opened a CAPA Request on February 6, 2017 (approved February 7, 2017) despite

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releasing updated risk assessments (e.g. Merlin@home Cybersecurity Risk Assessment: (b) (4) Rev. G) and releasing a new software version (Merlin@home EX2000 v8.2.2 - pilot release on December 7, 2016 and full release on January 9, 2017). Section 5 of the SOP defines the process and associated forms to produce during the CAPA process. Based on this process, the actions above should have been performed as part of the formal CAPA process to assess and respond to the identified issue.

**OBSERVATION 2**

Procedures for management review have not been adequately established.

Specifically, incomplete information was provided to the management review and medical advisory boards relative to the premature battery depletion issue. For example, a presentation to the Medical Advisory Board on November 11, 2014, and a similar presentation provided at a quarterly management review meeting on the following day, did not fully represent the rate of occurrence of premature battery depletion due to lithium cluster formation, and failed to note a death on (b) (4) (MDR # 2938836-2014-13599) that was strongly linked to this failure mode.

**OBSERVATION 3**

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, in 2014, St. Jude Medical formally requested Greatbatch to implement a design improvement to eliminate lithium cluster bridging in the 2850 battery header. The new battery design was (b) (4) . Despite the fact that this design change was made to reduce a serious risk to health posed by the device, St. Jude Medical failed to notify FDA of a correction until August 2016.

**OBSERVATION 4**

Products that do not conform to specifications are not adequately controlled.

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Specifically, ten ICDs that were subject to recall were shipped from a distribution center to a St. Jude US field representative after the recall was initiated on 10/11/2016. Additionally, seven ICDs that were subject to the recall were implanted between the dates of 10/14-26/2016.

## OBSERVATION 5

Design verification does not confirm that design output meets design input requirements.

Specifically, the firm did not fully verify all requirements of the Merlin@home device during their verification activities. For example, the Software System Requirement (b) (4) which states "the Remote Monitoring device shall only open network ports to authorized interfaces" which was implemented as Software Requirement Uploads (b) (4). The testing for the software requirement as defined in the Final Configuration Test Procedures (b) (4) Rev. H) partially verified the requirement by testing that the network ports opened with an authorized interface; however, they did not fully test the requirement by testing that network ports would not open with an unauthorized interface.

## OBSERVATION 6

Risk analysis is incomplete.

Specifically, the cybersecurity risk assessments for the Merlin@home ((b) (4) Rev B) and High Voltage devices ((b) (4) Rev A) did not accurately assess all known risks associated with the security of these devices at the time and therefore did not implement appropriate design inputs for the system. For example, the post-mitigation security risk ratings did not implement the findings from the (b) (4) (b) (4) Security Assessment from April 2, 2014 and the (b) (4) Cybersecurity Risk Assessment did not include all the vulnerabilities identified in the report. This resulted in the firm concluding that the identified threats were reduced to an acceptable level despite the findings of the third-party report and therefore did not identify and mitigate the security risks of their system.

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## Annotations to Observations

Observation 1: Promised to correct
Observation 2: Under consideration
Observation 3: Under consideration
Observation 4: Promised to correct
Observation 5: Under consideration
Observation 6: Promised to correct

## *DATES OF INSPECTION

2/07/2017(Tue),2/08/2017(Wed),2/09/2017(Thu),2/10/2017(Fri),2/13/2017(Mon),2/14/2017(Tue),2/15/2017(Wed),2/17/2017(Fri)

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