UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 1, 2015**

ST. JUDE MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Minnesota	**1-12441**	**41-1276891**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One St. Jude Medical Drive, St. Paul, MN	**55117**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(651) 756-2000**

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

On October 1, 2015, St. Jude Medical, Inc. (the "Company") received a warning letter dated September 30, 2015 from the Food and Drug Administration (the "FDA") related to observed non-conformities with Current Good Manufacturing Practice at its Atlanta, Georgia facility, the facility where the Company manufactures its CardioMEMS HF system. A copy of the warning letter is provided with this filing as Exhibit 99.1. This warning letter is specific to this facility and does not impact any of the Company's other manufacturing facilities.

The FDA inspected the Company's Atlanta manufacturing facility from June 8, 2015 to June 26, 2015. On July 6, 2015, the FDA issued a Form 483 identifying certain observed non-conformities with Current Good Manufacturing Practice. Following the receipt of the Form 483, the Company provided written responses to the FDA detailing corrective actions underway to address FDA's observations.

Since the completion of the FDA inspection, the Company has provided and will continue to provide the FDA with regular monthly updates, and the FDA warning letter acknowledges the actions already taken by the Company to address the observations. The Company is in the process of working diligently to completely remediate the FDA's observations for the Atlanta facility and fully integrate this former CardioMEMS stand-alone facility into St. Jude Medical's quality systems.

The warning letter does not identify any specific concerns regarding the performance of, or indicate the need for any field or other action regarding, the CardioMEMS product or any other St. Jude Medical product. The Company will continue manufacturing and shipping product from the Atlanta facility, and customer orders are not expected to be impacted while we work to resolve the FDA's concerns. The Company takes these matters seriously, will respond timely and fully to the FDA's requests, and believes that the FDA's concerns can be resolved without a material impact on the Company's financial results.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

99.1 Department of Health and Human Services, Food and Drug Administration, Warning Letter.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ST. JUDE MEDICAL, INC.

Date: October 2, 2015

By: /s/ Jason Zellers
Jason Zellers
Vice President, General Counsel
and Corporate Secretary

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
99.1	Department of Health and Human Services, Food and Drug Administration, Warning Letter

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309
Telephone: 404-253-1161
FAX: 404-253-1202

September 30, 2015

VIA UPS

Daniel J. Starks
President and Chief Executive Officer
St. Jude Medical, Inc.
One Street Jude Medical Drive
St. Paul, MN 55117

WARNING LETTER
(15-ATL-13)

Dear Mr. Starks:

During an inspection of St. Jude Medical (CardioMems), 387 Technology Circle, Atlanta, Georgia on June 08 – 26, 2015, investigators from the U.S. Food and Drug Administration (FDA) determined that your firm manufactures various medical devices such as the Cardiomems HF System. These products are devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 United States Code (U.S.C.) § 321(h)] in that they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act [21 U.S.C. § 351(h)] in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulations found at Title 21 of the Code of Federal Regulations Part 820 (21CFR Part 820).

A FORM FDA 483 Inspectional Observations, was issued to Mr. Jeff H. Kim, Director of Quality Assurance Engineering, at the end of our inspection (copy enclosed). We have received your responses dated July 15, 2015 and August 13, 2015, concerning our investigators' observations identified on the 483. We address these responses below, in relation to each of the noted violations. The violations documented on the FDA 483 issued include, but are not limited to, the following:

1. Corrective and preventive action activities and/or results have not been adequately documented in accordance with 21 CFR 820.100(b). Specifically, our inspection determined that your firm has not maintained an effective CAPA system and has not adequately investigated known problems identified through customer complaints, non-conformances, and other sources in accordance with your established CAPA procedures titled, Corrective & Preventive Action, SOP-603, Rev 12. During our inspection, deficiencies were observed in the documentation/investigations for the following CAPAs:

A. The investigation for CAPA 14-005 (issued on 11/26/2014 for incorrect serial numbers on hospital units) has not been closed and an extension form was issued to the CAPA file during the current inspection dated 6/8/2015. The due date for completion of the investigation into these occurrences was 1/18/2015.

   Your response letter dated August 13, 2015, indicates that the target date for complete effectiveness verification and closure for CAPA 14-005 is September 2015. We request that you submit copies of these activities to our office for evaluation.

B. The investigation for CAPA 14-004 (issued 11/5/2014 for defects found in coated sensors, i.e., a lack of adhesion uniformity, coating imperfections, and fractured glass) was due on 12/05/2014. However, this CAPA investigation is currently outstanding. A CAPA extension request was signed 6/9/2015 during the current inspection.

   Your response letter dated August 13, 2015, indicates that the target date for complete effectiveness verification and closure for CAPA 14-004 is January 2016. We request that you submit copies of these activities to our office for evaluation.

C. The impact assessment due date for CAPA 14-003 (issued on 9/25/2014 for hospital units returned from the field for "failing to boot") was set for 10/24/2014. This assessment was documented and approved by quality on 12/18/2014. No justification for an extension for completion of the impact assessment is documented. The investigation was due 1/19/2015 and was concluded 2/5/2015. QA's approval of the investigation is incomplete.

   Your response letter dated August 13, 2015, indicates that the target date for complete corrective actions for CAPA 14-003 is October 30, 2015. We request that you submit copies of these activities to our office for evaluation.

2. Process validation activities have not been documented and approved, in accordance with 21 CFR 820.75(a). Specifically, your established procedure, SOP-000110 titled EO Sterilization Validation and Requalification Procedure, specifies that your firm will perform an annual re-validation of the CardioMEMS HF System sterilization process. The most recent re-validation was performed on 10/23/2013.

   Your response letter dated August 13, 2015, indicates that your corrective actions for this observation will be completed in the 3rd Quarter of 2015. We request that you submit copies of these activities to our office for evaluation.

3. Production processes were not developed, conducted, controlled, and monitored to ensure that a device conforms to its specifications, as required by 21 CFR 820.70(a). Specifically, the silicone coating process for your medical devices has not been adequately validated. Your firm opened a CAPA in November 2014 in response to a lack of adhesion uniformity in the silicone coating, fractured glass, and coating imperfection. During your investigation, your firm performed one qualification study of 30 HF sensors; however, there is no documentation of the established parameters used at processing and no documentation showing repeatability of the HF coating process.

   Your response letter dated August 13, 2015, indicates that your firm's re-validation effort is on track for completion in September 2015 (pending the results of the root cause investigation being

conducted as part of CAPA 14-004). We request that you submit copies of these activities to our office for evaluation.

4. Procedures for quality audits have not been adequately established, as required by 21 CFR 820.22. Specifically, your firm's internal audit procedures titled, Internal Audit, SOP-101, has not been adequately implemented. For example, Section VI., states that supplier files will be reviewed on an annual basis per the approved internal audit schedule. This SOP also states that the auditor will examine all the supplier files for components that are used in the assembly of the Heart Failure Sensor and Delivery System. The Supplier Questionnaire and Acknowledgement Form, F-000104B, for the supplier of the coated HF Sensor with wire basket was signed by the supplier on 4/17/2014. The internal audit of the quality system (Internal Audit Number: IA-14-001) took place on 8/4/2014 - 8/6/2014. However, the QA Review Signature and Date portion of this Supplier Questionnaire and Acknowledgement Form, F-000104B, was completed during this inspection on 6/17/2015.

   Your response letter dated August 13, 2015, indicates that in response to this observation, your firm is in the process of executing and completing Quality Plan QP-15-06. This procedure was released to identify and review the status of all supplier files per the requirements of the Supplier Evaluation and Audit Procedure, SOP-104. Your letter indicates that these corrective actions are on track to be completed on October 2, 2015. We request that you submit copies of these activities to our office for evaluation.

We acknowledge the corrective actions your firm has implemented in regard to the FDA 483 observations that are not discussed in this letter. Those corrective actions appear to adequately address the observations identified on the FDA 483, but will require verification during our next inspection at your facility.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify our office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Derek Price, Compliance Officer, Atlanta District Office, 60 Eighth Street NE, Atlanta, Georgia, 30309. If you have any questions about the contents of this letter, please contact: Compliance Officer Price by phone at (404) 253-2277 or by fax at (404) 253-1201.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,

Ingrid A. Zambrana
District Director
Atlanta District Office

Cc: Mr. Jeff Kim,
Director of Quality Assurance Engineering
St Jude Medical (CardioMEMS)
387 Technology Cir NW Ste 500
Atlanta, GA 30313-2424

Enclosure