

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

ST JUDE MEDICAL INC

CIK:[203077](#) | IRS No.: [411276891](#) | State of Incorp.:**MN** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: [001-12441](#) | Film No.: **13527045**
SIC: **3845** Electromedical & electrotherapeutic apparatus

Mailing Address

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**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): **January 11, 2013**

ST. JUDE MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Minnesota
(State or other jurisdiction
of incorporation)

1-12441
(Commission
File Number)

41-1276891
(IRS Employer
Identification No.)

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

55117
(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))
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Item 8.01 Other Events.

On January 11, 2013, St. Jude Medical, Inc.'s (the "Company") Implantable Electronic Systems Division (formerly known as its Cardiac Rhythm Management Division) received a warning letter dated January 10, 2013 from the U.S. Food and Drug Administration (the "FDA") related to observed non-conformities with Current Good Manufacturing Practice at the Company's Implantable Electronic Systems Division's Sylmar, California facility. This warning letter is specific to the Company's Sylmar, California facility and does not impact any of the Company's other manufacturing facilities. As previously disclosed by management on its third quarter earnings call on October 17, 2012, this warning letter was expected.

The FDA inspected the Company's Sylmar, California manufacturing facility from September 25 to October 17, 2012. On October 17, 2012, the FDA issued a Form 483 (the "Form 483") identifying certain observed non-conformities with Current Good Manufacturing Practice. Following the receipt of the Form 483, the Company's Implantable Electronic Systems Division provided written responses to the FDA detailing proposed corrective actions and immediately initiated efforts to address FDA's observations of non-conformity. The warning letter relates to the observations reflected in the Form 483.

The FDA letter notes that it will not grant requests for exportation certificates to foreign governments or approve pre-market approval applications for Class III devices to which the quality system regulation deviations are reasonably related until the violations have been corrected. The warning letter does not, however, identify any specific concerns regarding the performance of, or indicate the need for any field or other action regarding, the Riata ST Optim or Durata leads or any other St. Jude Medical product. Accordingly, the Company will continue manufacturing and shipping product from the Sylmar facility and customer orders are not expected to be impacted while we work to resolve the FDA's concerns.

The Company takes this matter seriously and has already begun to respond to the FDA's requests. The Company is giving the highest priority to fully remediating these concerns.

Consistent with the Company's prior disclosures on this matter, the Company has taken the appropriate regulatory circumstances into account in managing its business and setting investor expectations, and believes the FDA's concerns can be resolved without a material impact on the Company's financial results. The Company will provide financial guidance for 2013 which will incorporate any impact from this warning letter on its fourth quarter earnings call scheduled for January 23, 2013.

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: January 14, 2013

By: /s/ Jason Zellers

Jason Zellers
Vice President, General Counsel
and Corporate Secretary