THORATEC CORP
Form 8-K
January 12, 2012

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 4, 2012**

THORATEC CORPORATION

(Exact name of Registrant as Specified in its Charter)

California	**000-49798**	**94-2340464**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

6035 Stoneridge Drive, Pleasanton, California	**94588**
(Address of Principal Executive Offices)	(Zip Code)

Registrant s telephone number, including area code **(925) 847-8600**

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

Thoratec Corporation, a California corporation (Thoratec or the Company), received a Warning Letter from the U.S. Food and Drug Administration (FDA) on January 4, 2012. The Warning Letter relates to the late filing of two Medical Device Reports (MDRs) by Thoratec, which were originally discussed in a Form 483 issued by FDA after an inspection of the Company s California manufacturing facilities in August and September 2011.

The Company takes these matters seriously and expects to respond to the FDA s requests within the required time frame. Following the receipt of the Form 483, we provided written responses to the FDA detailing proposed preventive and corrective actions and immediately initiated efforts to address FDA s observations. The FDA Warning Letter indicates that, with respect to the Form 483 observations unrelated to MDRs, Thoratec s responses provided during and after the inspection appeared to be adequate.

The Company believes that the FDA s concerns set forth in the Warning Letter can be resolved without a material impact to the Company s financial results. In particular, we do not expect either customer orders or our ability to manufacture or ship products to be impacted by the Warning Letter.

This Form 8-K may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements can be identified by the words, believes, views, expects, plans, projects, hopes, could, will, and other similar words. Actual results, events or performance could differ materially from these forward-looking statements based on a variety of factors, many of which are beyond Thoratec s control. Therefore, readers are cautioned not to put undue reliance on these statements. Investors are cautioned that all such statements involve risks and uncertainties, including risks related to regulatory approvals, the effects of FDA regulatory requirements, and our ability to address issues raised by FDA inspections adequately and on a timely basis without a resulting recall of product or interruption of manufacturing or shipment of products. Forward-looking statements contained in this press release should be considered in light of these factors and those factors discussed from time to time in Thoratec s public reports filed with the Securities and Exchange Commission, such as those discussed under the heading, Risk Factors, in Thoratec s most recent annual report on Form 10-K and in Thoratec s first quarter 2011 quarterly report on Form 10-Q, and as may be updated in subsequent SEC filings. These forward-looking statements speak only as of the date hereof. Thoratec undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

SIGNATURES

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

THORATEC CORPORATION

By: /s/ Gerhard F. Burbach
Gerhard F. Burbach
President and Chief Executive Officer

Date: January 12, 2012