

THORATEC CORP
Form 8-K
March 04, 2014

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): **March 4, 2014**

THORATEC CORPORATION

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction
of incorporation)

000-49798
(Commission
File Number)

94-2340464
(IRS Employer
Identification No.)

6035 Stoneridge Drive

Pleasanton, California 94588

(Address of principal executive offices including zip code)

(925) 847-8600

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(Registrant's telephone number, including area code)

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 (see General Instruction A.2. below):

- ☐ 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 7.01. Regulation FD Disclosure.

On Tuesday, March 4, 2014, Thoratec Corporation (Thoratec or the Company) issued a press release, which is furnished herewith as Exhibit 99.1, regarding the initiation of a voluntary worldwide medical device correction notification relating to the HeartMate II® LVAS Pocket System Controller.

As of February 4, 2014, Thoratec has received reports of four patient deaths occurring during attempts to exchange Pocket System Controllers, representing 0.2% of the applicable patient population. Thoratec has updated the HeartMate II LVAS labeling and training materials, is notifying all hospitals using Pocket System Controllers of this risk, and is recommending additional training for patients and caregivers. This Notification does not involve the return or exchange of any products.

Thoratec does not anticipate any material financial impact from this action.

The information in this Current Report on Form 8-K, including the exhibit, is furnished pursuant to Item 7.01 and shall not be deemed filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section. Furthermore, the information in the Current Report on Form 8-K, including the exhibit, shall not be deemed to be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended.

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, anticipates, believes, views, expects, 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 growth of existing markets for our products, customer and physician acceptance of Thoratec products, the effects of FDA regulatory requirements, our ability to address quality issues adequately and on a timely basis without a resulting recall of products or interruption of manufacturing or shipment of products, and the effects of competition. Forward-looking statements contained in this Form 8-K 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, quarterly reports on Form 10-Q, current reports on Form 8-K and other 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release of Thoratec Corporation, dated March 4, 2014.

SIGNATURES

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.

Dated as of March 4, 2014

THORATEC CORPORATION

By: /s/ Taylor C. Harris

Taylor C. Harris
Vice President and Chief Financial Officer

EXHIBIT INDEX

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