MASIMO CORP
Form 8-K
August 15, 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): August 14, 2014

MASIMO CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**001-33642**	**33-0368882**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
40 Parker		**92618**

Irvine, California
(Address of principal executive offices) (Zip Code)
Registrant s telephone number, including area code: (949) 297-7000

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 August 14, 2014, Masimo Corporation (Masimo) received a warning letter (the Warning Letter) from the U.S. Food and Drug Administration (FDA) regarding compliance with current Good Manufacturing Practices at Masimo s Irvine, California manufacturing facility. The Warning Letter follows an FDA inspection that concluded in October 2013. As previously disclosed, at the conclusion of that inspection, the FDA issued Masimo a Form 483 Inspectional Observations (the Form 483). Masimo responded to the Form 483 and provided information to the FDA in October and December 2013. The Warning Letter does not identify any new observations that were not included in the Form 483. A copy of the Warning Letter is filed as Exhibit 99.1 and is incorporated herein by reference.

Masimo takes the matters identified in the Warning Letter seriously and is in the process of evaluating what corrective actions, and associated costs, may be required to address the matters raised in the Warning Letter. Masimo is also in the process of preparing a response to the Warning Letter and intends to respond fully to the issues raised by the FDA within 15 business days as requested by the FDA and to work expeditiously to address those issues.

The Warning Letter does not restrict the manufacture, production or shipment of any of Masimo s devices, nor require the withdrawal of any product from the marketplace. Masimo will diligently work with the FDA to resolve the issues raised in the Warning Letter. However, failure to promptly address the issues raised in the Warning Letter to the FDA s satisfaction or to comply with U.S. medical device regulatory requirements in general could result in regulatory action being initiated by the FDA. These actions could include, among other things, product seizures, injunctions and civil money penalties.

Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, in connection with the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on current expectations about future events affecting us and are subject to risks and uncertainties, all of which are difficult to predict and many of which are beyond our control and could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements as a result of various risk factors, including, but not limited to: risks related to our assumptions regarding our ability to timely and effectively respond to the Warning Letter, additional actions by or requests from the FDA and unanticipated costs or delays associated with resolution of these matters; as well as other factors discussed in the Risk Factors section of our most recent reports filed with the Securities and Exchange Commission (SEC), which may be obtained for free at the SEC s website at www.sec.gov. Although Masimo believes that the expectations reflected in our forward-looking statements are reasonable, it does not know whether our expectations will prove correct. All forward-looking statements included in this Current Report on Form 8-K are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of today s date. Masimo does not undertake any obligation to update, amend or clarify these forward-looking statements or the Risk Factors contained in Masimo s most recent reports filed with the SEC, whether as a result of new information, future events or otherwise, except as may be required under the applicable securities laws.

Item 9.01. Financial Statements and Exhibits.
(d) Exhibits

99.1 FDA Warning Letter, dated August 12, 2014 and received on August 14, 2014.

SIGNATURES

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

MASIMO CORPORATION

Date: August 14, 2014

By: /s/ Mark P. Raad
Mark P. de Raad
Executive Vice President & Chief Financial Officer
(Principal Financial and Accounting Officer)