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): May 26, 2017

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.)

52 Discovery Irvine, California	92618
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933(§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events

On August 14, 2014, Masimo Corporation ("Masimo") announced that it had 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.

On May 26, 2017, Masimo received a letter from the FDA indicating that FDA has completed an evaluation of Masimo's corrective actions in response to the Warning Letter, and that, based on the FDA's evaluation, it appears that Masimo has addressed the violations contained in the Warning Letter. The letter indicated that future FDA inspections and regulatory activities will further assess the adequacy and sustainability of the corrections. A copy of the letter is filed as Exhibit 99.1 and is incorporated herein by reference.

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 whether the corrective actions taken have addressed all violations contained in the Warning Letter, additional or future 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 May 25, 2017 and received on May 26, 2017.

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: June 5, 2017

By: /s/ TOM MCCLENAHAN

Tom McClenahan

Executive Vice President & General Counsel

Exhibit 99.1

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

May 25, 2017

Mr. Joe Kiani, Chief Executive Officer
Masimo Corporation
52 Discovery
Irvine, CA 92618

Dear Mr. Kiani:

The Food and Drug Administration has completed an evaluation of your corrective actions in response to our Warning Letter (WL#31-14), dated 08/12/14. Based on our evaluation, it appears that you have addressed the violations(s) contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of theses corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

Kelly D. Sheppard -S

Digitally signed by Kelly D. Sheppard -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000425614, cn=Kelly D. Sheppard -S
Date: 2017.05.25 11:51:17 -07'00'

Kelly D. Sheppard
Acting Program Division Director
Division3/West
Office of Medical Device and Radiological Health Operations

KS:rwb

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