

MASIMO CORP
Form 8-K
November 15, 2010

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): November 4, 2010

MASIMO CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33642
(Commission
File Number)

33-0368882
(IRS Employer
Identification No.)

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40 Parker

Irvine, California
(Address of principal executive offices)

92618
(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 or about November 4, 2010, Masimo Corporation voluntarily notified the U.S. Food and Drug Administration (FDA) that it recently received allegations regarding the safety and efficacy of Masimo's Pronto and Pronto-7 products from certain former sales representatives of the Company. Although Masimo continues to believe that it is in substantial compliance with all healthcare laws applicable to it, and that all the Company's products meet their product specifications, Masimo takes seriously any allegation regarding the safety and efficacy of any of its products. As a result, Masimo also is conducting an internal review regarding the matter. The Company intends to respond timely and fully to any response received from the FDA.

SIGNATURE

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 hereunto duly authorized.

MASIMO CORPORATION

Date: November 14, 2010

By: */s/* MARK P. DE RAAD
Mark P. de Raad
Executive Vice President, Chief Financial Officer & Secretary
(Principal Financial and Accounting Officer)