STRYKER CORP
Form 8-K
August 24, 2017

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: August 23, 2017

STRYKER CORPORATION
(Exact name of registrant as specified in its charter)

Michigan	000-9165	38-1239739
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2825 Airview Boulevard, Kalamazoo, Michigan (Address of principal executive offices)	49002 (Zip Code)

Registrant's telephone number, including area code:
269.385.2600

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 23, 2017, Stryker Corporation announced that the company has informed the U.S. Food and Drug Administration (FDA) of a voluntary product recall involving specific lots of Oral Care products sold through the company's Sage Products business unit (Sage). The recalled products contain Oral Care solutions manufactured for Sage by a third-party supplier and were distributed between July 2015 and August 2017. The recall is being initiated due to a potential for cross-contamination of Oral Care solutions manufactured by the third party on equipment shared with non-pharmaceutical products, as stated in a Warning Letter from FDA dated July 17, 2017. To date, Stryker has not been made aware of any serious adverse events associated with the Oral Care products recall. However, there have been some reports of minor irritation and allergic reaction. Stryker has discontinued business with the third-party supplier and all Oral Care solutions are being manufactured in-house by Sage. Stryker expects to resume shipping Oral Care products in September and anticipates a return to full supply capacity by year end.

Additionally, the FDA Warning Letter sets forth concerns regarding microbiological testing methods used for all products containing solutions sold by Sage. These include Oral Care solutions in the recalled products and solutions contained in cloth-based products manufactured by Sage. FDA indicated that products must now be tested using a verified compendial microbiological method, a growth-based method that requires more time to complete than the one previously used at Sage. Both methods can detect the presence of microorganisms, while the compendial method provides additional information about the type and number of microorganisms. As a result, in August, Stryker placed cloth-based products, which represents approximately 50% of Sage's revenue, on a temporary ship hold until they are tested using this method. Stryker anticipates it will resume shipping products manufactured by Sage and tested under the compendial method in September, and anticipates a return to full supply capacity by year end.

Forward-Looking Statements

Certain statements above may contain information that includes or is based on forward-looking statements within the meaning of the federal securities law that are subject to various risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in such statements. Such factors include, but are not limited to: unanticipated issues in addressing in a timely manner the Sage product-related issues discussed above; weakening of economic conditions that could adversely affect the level of demand for our products; pricing pressures generally, including cost-containment measures that could adversely affect the price of or demand for our products; changes in foreign exchange markets; legislative and regulatory actions; unanticipated issues arising in connection with clinical studies and otherwise that affect U.S. Food and Drug Administration approval of new products; potential supply disruptions; changes in reimbursement levels from third-party payors; a significant increase in product liability claims; the ultimate total cost with respect to the Rejuvenate and ABG II matter; the impact of investigative and legal proceedings and compliance risks; resolution of tax audits; the impact of the federal legislation to reform the United States healthcare system; changes in financial markets; changes in the competitive environment; our ability to integrate acquisitions; and our ability to realize anticipated cost savings. Additional information concerning these and other factors is contained in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

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.

STRYKER CORPORATION
(Registrant)

August 24, 2017 /s/ Glenn S. Boehnlein
Date Glenn S. Boehnlein
Vice President, Chief Financial Officer