STERIS CORP
Form 8-K
February 15, 2011

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) February 10, 2011

STERIS Corporation

(Exact name of registrant as specified in its charter)

Ohio	**1-14643**	**34-1482024**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5960 Heisley Road, Mentor, Ohio **44060-1834**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code (440) 354-2600

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 February 10, 2011, STERIS Corporation received a warning letter from the U.S. Food and Drug Administration regarding our Verify® SixCess Class 6 Challenge Packs and Verify SixCess Class 6 Chemical Indicators. These devices are intended for use in steam sterilization applications. The Verify SixCess Class 6 Challenge Packs and Verify SixCess Class 6 Chemical Indicators are not related to the STERIS SYSTEM 1E Liquid Chemical Sterilant Processing System.

This FDA warning letter claims that certain promotional materials related to these devices include incorrect statements and, as a result of those statements, the warning letter claims that these devices are misbranded under the U.S. Food, Drug and Cosmetic Act. The warning letter requests that STERIS respond within 15 working days from receipt of the letter. STERIS is reviewing this matter and expects to respond within that time period. We do not believe that the impact of this event will have a material adverse effect on our financial results.

This Form 8-K may contain statements concerning certain trends, expectations, forecasts, estimates, or other forward-looking information affecting or relating to the Company or its industry, products or activities that are intended to qualify for the protections afforded forward-looking statements under the Private Securities Litigation Reform Act of 1995 and other laws and regulations. Forward-looking statements speak only as to the date of this report, and may be identified by the use of forward-looking terms such as may, will, expects, believes, anticipates, plans, estimates, projects, targets, forecasts, outlook, impact, potential, confidence, improve, opt and seeks, or the negative of such terms or other variations on such terms or comparable terminology. Many important factors could cause actual results to differ materially from those in the forward-looking statements including, without limitation, disruption of production or supplies, changes in market conditions, political events, pending or future claims or litigation, competitive factors, technology advances, actions of regulatory agencies, and changes in laws, government regulations, labeling or product approvals or the application or interpretation thereof. Other risk factors are described herein and in the Company s Form 10-K and other securities filings. Many of these important factors are outside STERIS s control. No assurances can be provided as to any result or the timing of any outcome regarding the requests or submissions referenced in this Form 8-K or otherwise with respect to any regulatory action, administrative proceedings, government investigations, litigation, warning letters, consent decree, rebate program, transition, cost reductions, business strategies, earnings or revenue trends or future financial results. References to products, the consent decree, or the transition or rebate program, are summaries only and do not alter or modify the specific terms of the product clearance or literature or the decree or program. Unless legally required, the Company does not undertake to update or revise any forward-looking statements even if events make clear that any projected results, express or implied, will not be realized. Other potential risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements include, without limitation, (a) the potential for increased pressure on pricing that leads to erosion of profit margins, (b) the possibility that market demand will not develop for new technologies, products or applications or the Company s rebate program, transition plan or other business initiatives will take longer, cost more or produce lower benefits than anticipated, (c) the possibility that application of or compliance with laws, court rulings, certifications, regulations, regulatory actions, including without limitation those relating to previously disclosed FDA warning letters, government investigations, the December 3, 2009 or February 22, 2010 FDA notices, the April 20, 2010 consent decree and related transition plan and rebate program, the SYSTEM 1E device, the Reliance EPS System, the outcome of the pending requests and clearances referenced herein, or other requirements or standards may delay, limit or prevent new product introductions, affect the production and marketing of existing products or services or otherwise affect Company performance, results, prospects or value, (d) the potential of international unrest or effects of fluctuations in currencies, tax assessments or

rates, raw material costs, benefit or retirement plan costs, or other regulatory compliance costs, (e) the possibility of reduced demand, or reductions in the rate of growth in demand, for the Company s products and services, (f) the possibility that anticipated growth, cost savings, rebate assumptions, new product acceptance or approvals, including without limitation SYSTEM 1E and accessories thereto, or other results may not be achieved, or that transition, labor, competition, timing, execution, regulatory, governmental, or other issues or risks associated with our business, industry or initiatives including, without limitation, the consent decree, the transition from the SYSTEM 1 processing system, or those matters described in our Form 10-K for the year ended March 31, 2010 or other securities filings may adversely impact company performance, results, prospects or value, (g) the effect of the contraction in credit availability, as well as the ability of our and suppliers to adequately access the credit markets when needed, and (h) those risks described in our Annual Report on Form 10-K for the year ended March 31, 2010 and the Form 10-Q for the quarter ended December 31, 2010 and other securities filings.

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.

STERIS CORPORATION

By /s/ Mark D. McGinley
Mark D. McGinley
Senior Vice President, General Counsel, and Secretary

Date: February 15, 2011