# 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): December 3, 2009

# **STERIS Corporation**

(Exact Name of Registrant as Specified in Charter)

Ohio (State or Other Jurisdiction of Incorporation)

1-14643 (Commission File Number) 34-1482024 (IRS Employer Identification No.)

**5960 Heisley Road, Mentor, Ohio** (Address of Principal Executive Offices)

44060-1834 (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 December 4, 2009, the STERIS Corporation issued a press release discussing the U.S. Food and Drug Administration (the "FDA") December 3, 2009 notice addressed to healthcare facility administrators and infection control practitioners concerning the regulatory status of the STERIS System 1 processor. A copy of this press release is attached hereto as Exhibit 99.1

## Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 Press Release issued by STERIS Corporation on December 4, 2009.

## **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: December 4, 2009

## EXHIBIT INDEX

Exhibit No. 99.1 <u>Description</u>
Press Release issued by STERIS Corporation on December 4, 2009.

# STERIS STATEMENT IN RESPONSE TO DECEMBER 3, 2009 FDA NOTICE AND DEVELOPMENTS ON SYSTEM 1 WARNING LETTER

**MENTOR, OHIO** (December 4, 2009) – STERIS Corporation was notified on December 3, 2009 that the U.S Food and Drug Administration (FDA) had issued a notice to healthcare facility administrators regarding the regulatory status of the STERIS SYSTEM 1® Sterile Processing System, as well as actions healthcare facilities should take if they use this device.

"We disagree with the FDA's recent notice and are working to engage in further dialogue with the Agency about this matter. Since its introduction in 1988, we estimate that SYSTEM 1 Sterile Processing System has safely and effectively sterilized more than 300 million devices when used as directed," said STERIS President and Chief Executive Officer, Walt Rosebrough. "We understand our Customers' concerns and apologize for the inconvenience the FDA notice will cause to their sterilization and decontamination processes."

The FDA has stated that healthcare administrators should transition to acceptable alternatives to meet their sterilization and decontamination requirements. If they do not have an acceptable alternative, FDA has stated that Customers may continue to use SYSTEM 1 while they assess their sterilization requirements. FDA has also stated it is not aware of any confirmed cases of infection directly attributable to inadequate reprocessing by SYSTEM 1.

When considering the availability of acceptable alternatives to meet sterilization and disinfection needs, STERIS suggests that healthcare administrators include these considerations:

- Consult the device manufacturer's written instructions for reprocessing procedures.
- Be aware that not all devices can be reprocessed using the same sterilization technology.
- · Note that the healthcare facility's validation/verification requirements will need to be reviewed.

STERIS has established a dedicated hotline for more information – 440-392-7223 – if SYSTEM 1 users have immediate questions. STERIS will also continue to update Customers via <a href="https://www.steris.com">www.steris.com</a> as more information becomes available.

As a result of the December 3, 2009 FDA notice, the Company is considering its available options and expects to have further discussions with the FDA. There is no assurance, however, that the FDA will not pursue an administrative or enforcement action or not seek other remedies, including the demand that STERIS stop further sales of the SYSTEM 1 device and any related services, accessories and sterilant. These actions by the FDA could possibly result in administrative orders or judgments requiring re-labeling or restriction on the manufacturing, sale, or distribution of products, or could require us to take other actions, including recalls, to pay significant monetary fines or civil damages, or to be subject to other governmental or third party claims or remedies, which could materially affect our business, performance, value, financial condition, and results of operations.

Additional information regarding the FDA investigation of SYSTEM 1 is described in our Form 10-K for the fiscal year ended March 31, 2009 and the Form 10-Q for the quarter ended September 30, 2009.

#### **About STERIS:**

The mission of STERIS Corporation is to provide a healthier today and safer tomorrow through knowledgeable people and innovative infection prevention, decontamination and health science technologies, products and services. The Company has approximately 5,000 dedicated employees around the world working together to supply a broad array of solutions by offering a combination of equipment, consumables and services to healthcare, pharmaceutical, industrial and government Customers. The Company is listed

on the New York Stock Exchange under the symbol STE. For more information, visit www.steris.com.

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#### **Contacts:**

**Investors:** 

Julie Winter, Director, Investor Relations at 440-392-7245.

#### **News Media:**

Stephen Norton, Director, Corporate Communications at 440-392-7482

This news release may contain statements concerning certain trends, expectations, forecasts, estimates, or other forward-looking information affecting or relating to the Company or its industry 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," "potential," "confidence," "improve," "optimistic," "comfortable," "trend", 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 or government regulations or the application or interpretation thereof. Other risk factors are described 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 outcome from litigation, regulatory action, administrative proceedings, government investigations, warning letters, cost reductions, business strategies, level of share repurchases or dividends, earnings and revenue trends, expense reduction or other future financial results. 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 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, regulations, regulatory actions, including without limitation previously disclosed FDA warning letters, government investigations, and December 3, 2009 FDA notice, certifications or other requirements or standards may delay or prevent new product introductions, affect the production and marketing of existing products, or otherwise affect Company performance, results, 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 cost savings or other results may not be achieved, or that transition, labor, competition, timing, execution, regulatory, governmental, or other issues or risks associated with the matters described in this release, and the conference call referenced here, may adversely impact Company performance, results, or value, (q) the effect of the credit crisis on our ability, as well as the ability of our customers 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, 2009 and the Form 10-Q for the quarter ended September 30, 2009.