STAAR SURGICAL CO
Form 8-K
February 10, 2015

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 4, 2015

STAAR Surgical Company
(Exact name of registrant as specified in its charter)

Delaware		95-3797439
(State or other jurisdiction of incorporation)	0-11634 (Commission File Number)	(I.R.S. Employer Identification No.)
1911 Walker Ave, Monrovia, California (Address of principal executive offices)		91016 (Zip Code)

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

As previously disclosed, STAAR received an FDA Warning Letter, dated May 21, 2014, regarding compliance with current Good Manufacturing Practices at the Monrovia facility. Upon receipt of this letter, STAAR initiated development and subsequent implementation of corrective action plans related to this letter. Beginning on November 14, 2014 and continuing through February 4, 2015, the U.S. Food and Drug Administration (FDA) inspected the Company's Monrovia facility as a follow-up to the 2014 Warning Letter and also as a post-approval inspection regarding the approved PMA supplement that added the Monrovia facility as an alternate manufacturing facility for the ICL. On February 4, 2015, at the conclusion of the inspections, the FDA issued a Form 483 with ten inspectional observations. The observations focus primarily on the need for adherence to and improved procedures, processes and documentation relating to design change, design transfer into specifications and production, verification and validation associated with device design and production, improvement in Good Documentation Practices, and broader environmental monitoring.

STAAR is currently drafting a response to the FDA's observations and is concurrently continuing to develop and implement its corrective action plans relating to the 2014 Warning Letter and the Form 483. STAAR takes the matters identified by FDA seriously and will continue to work diligently to address the observations identified in the Form 483 and 2014 Warning Letter. STAAR has enhanced and continues to enhance its overall quality program as we focus on remediating all elements identified.

There can be no assurance that the FDA will be satisfied with the Company's response. Unless and until STAAR is able to correct outstanding issues to the FDA's satisfaction, the FDA may withhold approval of new products such as the Toric ICL (TICL) or take additional regulatory or legal action against the Company. Any such further action could have a material and negative impact on the Company's ongoing business and operations.

A Caution Concerning Forward-Looking Statements

This report on Form 8-K includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that are subject to risks, uncertainties and other factors, including but not limited to risks related to whether the FDA or other regulatory authorities will agree that steps taken or to be taken by STAAR to correct matters described in the 2014 Warning Letter and Form 483 are adequate, whether STAAR can resolve any continuing concerns that may be expressed by the FDA or other regulatory authorities in a timely manner and whether the FDA or other regulatory authorities decide to take further corrective or disciplinary actions against STAAR. These risks, uncertainties and other factors could adversely cause the Company's actual results and future business prospects to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements, and to review the Company's Annual Report on Form 10-K for the year ended January 3, 2014, and also in the Company's Quarterly Report on Form 10-Q for the quarter ended July 4, 2014, under the headings "Risk Factors," and "Management Discussion and Analysis of Financial Condition and Results of

Operations,” both of which are on file with the Securities and Exchange Commission and available in the "Investor Information" section of the Company’s website (www.STAAR.com) under the heading "SEC 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.

February 10, 2015 By: /s/ Barry G. Caldwell
Barry G. Caldwell
President and Chief Executive Officer