STAAR SURGICAL CO
Form 8-K
February 02, 2005

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 1, 2005

STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware	0-11634	95-3797439
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

1911 Walker Avenue, Monrovia, California, 91016

(Address of principal executive offices) (Zip Code)

(Registrant's telephone number, including area code): (626) 303-7902

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 7.01. Regulation FD Disclosure.

As previously announced, on September 23, 2004, the FDA completed an inspection of the Company s Monrovia, California manufacturing facility and issued a form FDA 483 Inspectional Observations (the 483 Observations). On November 4, 2004, the Company submitted its written response to the 483 Observations and provided supplemental information on December 20, 2004.

On January 27, 2005, the Company and its representatives met with the FDA to update them on the corrective actions taken by the Company in response to the 483 Observations. During the meeting, the FDA gave no indication of the status of their review of our response or the nature or timing of future communications to the Company.

In conversations, the FDA confirmed with the Company s regulatory counsel with respect to the Collamer material that materials issues with regard to stability have been addressed to the FDA s satisfaction.

On December 16, 2004, the Company submitted to the FDA a supplement to the Company s investigational device exemptions application for the STAAR Myopic Implantable Contact Lens (ICL). The supplement requested permission for each of the active clinical centers to continue enrollment of eyes in the ICL clinical investigation while the pre-market approval is pending with the FDA so that the physicians may continue to expand on their clinical experience with implantation of the ICL. On January 14, 2004, the FDA approved the supplement allowing 18 investigational sites to enroll a combined total of 75 additional eyes each month.

Until the FDA is satisfied with the adequacy of the Company s corrective action, it may take further actions which could include conducting another inspection, seizure of the Company s products, injunction of the Monrovia facility to compel compliance (which may include suspension of production operations and/or recall of products), or other actions. Such actions could have a material adverse effect on the Company s established lines of business, results of operations and liquidity. Furthermore, until the FDA is satisfied with the Company s response, it is unlikely to grant the Company approval to market the ICL in the United States.

The Company is not able to predict whether the FDA will conclude that the Company s corrective actions to date or those included in its response to the 483 Observations satisfactorily resolve its concerns. Nor can the Company predict the likelihood, nature of, or timing of any additional action by the FDA or the impact of the 483 Observations or any other FDA action on the Company s established lines of business, results of the operations or liquidity or the approval of the ICL for the United States market.

The business of the Company is subject to numerous risks and uncertainties that are beyond its control, including, but not limited to, those set forth above and in the other reports filed by the Company with the Securities and Exchange Commission. Such risks and uncertainties could have a material adverse effect on the Company s business, financial condition, operating results and cash flows.

The information in this Current Report on Form 8-K will not be treated as filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the Exchange Act) or otherwise subject to the liabilities of that section. This information will not be incorporated by reference into a filing under the Securities Act of 1933, or into another filing under the Exchange Act.

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 thereunto duly authorized.

Date: February 1, 2005

STAAR SURGICAL COMPANY

By: /s/ John Bily

John Bily
Chief Financial Officer