STAAR SURGICAL CO
Form 8-K
July 20, 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): July 15, 2005

STAAR Surgical Company

(Exact name of registrant as specified in its charter)

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

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

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))

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Item 8.01 Other Events.

As a manufacturer of medical devices, STAAR Surgical Company's manufacturing processes and facilities are subject to regulation by the U.S. Food and Drug Administration (the "FDA"). The FDA inspects STAAR's facilities from time to time to determine whether we are in compliance with quality system regulations relating to such things as manufacturing practices, validation, testing, quality control and product labeling, and in compliance with FDA medical device reporting obligations.

On July 5, 2005 STAAR received a letter from the FDA (the "FDA Letter") relating to a List of Inspectional Observations ("Form 483"), which the FDA had delivered to STAAR on September 23, 2004 at the conclusion of the FDA's most recent inspection of STAAR. The FDA Letter referred to STAAR's letter responding to the Form 483 observations (the "November 2004 Response"), which STAAR had delivered to the FDA on November 4, 2004 and updated by letter on February 11, 2005.

The FDA Letter requested that STAAR provide additional information related to the Form 483 observations, and presented the FDA's conclusion that based on STAAR's earlier responses STAAR had "failed to adequately correct numerous violations" noted in the Form 483. The FDA Letter gave STAAR ten calendar days from its receipt of the letter to provide responses and supporting documentation. The letter covers 14 of the 36 original Form 483 observations, and requests specific information on 27 of the 84 original sub-observations in the Form 483. A copy of the FDA Letter is attached to this report as Exhibit 99.1 and is incorporated herein by this reference.

On July 15, 2005 STAAR provided its response to the FDA by letter (the "Response Letter") within the ten-calendar-day deadline. The Response Letter, together with 120 exhibits, comprised 15 volumes and provided a substantive and detailed response on each of the 27 sub-observations. The responses included requested documentation, updates on corrective actions taken by STAAR following the inspection that ended in September 2004 and following STAAR's November 2004 Response, and information gathered after those dates. On three points where the FDA disagreed with STAAR's interpretation of the FDA regulations, STAAR provided information showing compliance with the regulations under the FDA's interpretation or corrective actions undertaken to achieve compliance in accordance with the perspective provided by the FDA.

STAAR also responded to the concerns expressed in Footnote 1 of the FDA Letter, where the FDA suggested that STAAR "conduct a thorough review of your records, processes, and operations to determine whether you are in compliance with the Act and applicable FDA regulations" and requesting that STAAR "immediately correct all of your violations." In response to this concern, STAAR described the comprehensive review of its quality system undertaken following receipt of the FDA's Warning Letters dated December 22, 2003 and April 23, 2004. Since that time, with the assistance of Quintiles Consulting, STAAR developed a comprehensive Global Quality Systems Action Plan ("QSAP"). The QSAP was completed in April 2004, and the initial version was provided to the FDA on May 14, 2004.

STAAR described to the FDA the significant resources devoted to implementing the QSAP and STAAR's continuous updating of the QSAP to incorporate feedback from both internal and external sources. This has included addressing the issues identified in the FDA's Form 483 observations and additional evaluations and observations made by KEMA Registered Quality, Inc. and consultants at King & Spalding LLP. STAAR provided a current copy of the revised QSAP along with the Response Letter.

STAAR cannot predict the timing or substance of the FDA's reaction to the Response Letter. The FDA may elect to re-audit STAAR's quality systems and medical device reporting systems before giving a definitive response. However, STAAR can give no assurance that the FDA will not respond more rapidly.

STAAR believes that the FDA will pursue enforcement action against STAAR if it finds the information provided in the Response Letter to be inadequate. FDA enforcement action, if taken, would most likely have a material and adverse impact on STAAR and its prospects, and can include seizure of products or an injunction requiring STAAR to suspend some or all of its U.S. distribution for a period of six months or more.

STAAR believes that the FDA is unlikely to approve marketing of the VISIAN® ICL in the U.S. while enforcement or other similar proceedings are pending. In part, this is because STAAR must be deemed compliant with the FDA's Quality System Regulations and Medical Device Reporting Regulations before final marketing approval of the VISIAN ICL will be authorized.

All statements in this report that are not statements of historical fact are forward-looking statements, including statements about actions that may be taken by the FDA, and any other statements of the plans, strategies, and objectives of management for future operations, any statements concerning proposed new products and government approval of new products, services or developments, statements of belief and any statements of assumptions underlying any of the foregoing. These statements are based on expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those described in the forward-looking statements. The risks and uncertainties include the outcome of our proceedings with the FDA Office of Compliance, including our response to the letter received from the FDA on July 5, 2005, our ability to implement our cost savings strategies and realize our expected savings, our limited capital resources, the success of our efforts in realigning our management team, our ability to reverse the decline in domestic sales of IOLs, our ability to maintain or enhance our existing product sales and gross profit margin and reduce compliance expenditures, the need to obtain regulatory approval for new products, acceptance of new products by medical practitioners and consumers, the rapid pace of technological change in the ophthalmic industry, our ability to compete with much larger ophthalmic companies, general domestic and international economic conditions, access to financing and other factors beyond the control of STAAR Surgical Company, including those

detailed from time to time in STAAR Surgical Company's reports filed with the Securities and Exchange Commission. STAAR Surgical Company assumes no obligation to update these forward-looking statements to reflect future events or actual outcomes and does not intend to do so.

Item 9.01 Financial Statements and Exhibits.

Exhibit 99.1 Letter from U.S. Food and Drug Administration dated June 30, 2005.

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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.

STAAR Surgical Company

July 19, 2005

By: /s/ David Bailey

Name: David Bailey
Title: Chief Executive Officer

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Exhibit Index

Exhibit No.	Description
99.1	Letter from U.S. Food and Drug Administration dated June 30, 2005.