STAAR SURGICAL CO
Form 8-K
June 27, 2007

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): June 26, 2007

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 7.01 Regulation FD Disclosure.

Item 8.01 Other Events

On June 26, 2007, the Company received a Warning Letter from the U.S. Food and Drug Administration ("FDA") citing four areas of noncompliance noted during an inspection of the Company's clinical study procedures, practices, and documentation related to the Toric Implantable Collamer Lens ("TICL"). The inspection was conducted by the Bioresearch Monitoring Program of the FDA Office of Regulatory Affairs ("BIMO") between February 15 and March 14, 2007. The Warning Letter notes deviations from FDA regulations that occurred between 2002 and 2005, which were among eight matters observed in the Inspectional Observations on FDA Form 483 received by the Company at the conclusion of the BIMO inspection. The Company described these observations in its Current Report on Form 8-K filed with the SEC on March 14, 2007, and provided the FDA with a written response to the Inspectional Observations on April 5, 2007.

Noting that the FDA staff found some of the Company’s responses in the April 5 letter inadequate, the Warning Letter has instructed the Company to provide additional corrective and preventative action plans and further information on some of the corrective actions described in the Company’s April 5 letter. The Company expects to provide its written response on or before July 18, 2007, the deadline for response stated in the Warning Letter.

David Bailey, President and CEO of STAAR Surgical Company, is expected to discuss the Warning Letter during a webcast presentation at the Jefferies Healthcare Conference, scheduled for 1:00 pm Eastern Time on Thursday, June 18, 2007. The webcast may be publicly accessed through the Investor Information page of the Company’s website at www.staar.com.

The Company has revised key processes involved in initiating and monitoring clinical studies, and anticipates that an enhancement of its processes and procedures, a detailed discussion of their intended corrective effect, and a satisfactory projected completion date will adequately address the concerns of the FDA expressed in the Warning Letter. However, if the FDA does not find the Company’s response adequate, further administrative action could follow, including actions that could delay approval of the TICL or restrict the Corporation as a sponsor of clinical investigations.

BIMO inspections are part of a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE), Premarket Approval (PMA) applications, and Premarket Notification submissions (510k) are scientifically valid and accurate. Another objective of the program is to ensure that human subjects are protected from undue hazard or risk during the course of scientific investigations. While the past procedural violations noted in the Warning Letter are serious in nature and require comprehensive corrective and preventative actions, the Company does not believe that these nonconformities undermine the scientific validity and accuracy of its clinical data, or that human subjects were subjected to undue hazard or risk.

The description of the Warning Letter in this Report is qualified in its entirety by reference to the text of the Warning Letter, a copy of which is attached to this Report as Exhibit 99.1 and is incorporated herein by this reference.

All statements in this report that are not statements of historical fact are forward-looking statements, including statements about actions that may or may not be taken by the FDA, statements of the Company’s expectations or belief and any statements of assumptions underlying 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 FDA’s discretion in determining the adequacy of the Company’s response to the Warning Letter, the FDA’s discretion to issue additional warning letters or take other regulatory action as a result of inspectional observations or other data received by the agency, the risk that for serious violations of regulations related to clinical procedures FDA enforcement actions may result in penalties, injunctions or other measures, and the general risks to the Company’s business that result from FDA regulation, which are described in greater detail in our Quarterly Report on Form 10-Q filed on May 9, 2007, under the headings "Risk Factors - We are subject to extensive government regulation, which increases our costs and could prevent us from selling our products," and "Risk Factors - FDA compliance issues have harmed our reputation, and we expect to devote significant resources to maintaining compliance in the future," and the other risks describe in the Risk Factors section of that report and detailed from time to time in our other 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.

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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

June 27, 2007

By: /s/David Bailey

Name: David Bailey
Title: President and Chief Executive Officer

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Exhibit Index

Exhibit No.	Description
99.1	Warning Letter dated June 26, 2007 from U.S. Food and Drug Administration.