STAAR SURGICAL CO
Form 8-K
September 15, 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): September 14, 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 7.01 Regulation FD Disclosure.

On September 14, 2005, representatives of the Los Angeles District Office of the United States Food and Drug Administration (the "FDA") completed an inspection of the Company's Monrovia, California facility, which began on August 29, 2005. The inspection included both a pre-approval inspection in connection with the Company's premarket approval application for the VISIAN® ICL (the "PMA") and an audit of the Company's compliance with the FDA's Quality System Regulation and Medical Device Reporting regulations.

At the conclusion of the inspection the inspectors issued three Inspectional Observations on FDA Form 483 (the "Observations"). One of the Observations was annotated as "corrected and verified," and the Company promised to correct the remaining two. Based on the Company's corrections to the quality system issues identified by the FDA in previous inspections and the findings of the FDA in this inspection, the Company does not believe that enforcement action by the FDA is likely at this time.

The Company believes the outcome of the inspection reflects the Company's efforts to enhance its compliance systems over the past 20 months and the FDA's evaluation of that work.

As the Company previously announced, it received a letter from the FDA on July 28, 2005 stating that the PMA for the VISIAN ICL is approvable subject to an FDA inspection that finds the Company's manufacturing facilities, methods and controls in compliance with the applicable requirements of the FDA's Quality System Regulation. Accordingly, the issuance of a final approval letter for the VISIAN ICL remains subject to a review of the results of the recent inspection by the FDA's Center for Devices and Radiological Health.

Forward Looking Statements

All statements in this report that are not statements of historical fact are forward-looking statements, including any statement about the likelihood of FDA enforcement action or regulatory approval of the Company's products. These statements are based on expectations and assumptions as of the date of this report 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, which could affect commercial distribution of the VISIAN ICL in the U.S. and could result in restrictions on our ability to continue our business as well as harm to our reputation and stock price, and other factors beyond our control, including those detailed from time to time in our reports filed with the Securities and Exchange Commission. The 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

September 14, 2005

By: /s/ David Bailey

Name: David Bailey
Title: Chief Executive Officer