STAAR SURGICAL CO
Form 8-K
July 11, 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 5, 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 July 11, 2005, the Company published a press release announcing its receipt of a letter from the United States Food and Drug Administration. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated herein by this reference.

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.

Between July 28 and September 23, 2004 the FDA conducted its most recent inspection of STAAR's Monrovia, California facility. During this inspection the FDA investigators observed violations of the FDA's Quality System Regulations and Medical Device Reporting Regulations and documented these observations in a List of Inspectional Observations ("Form 483") delivered to STAAR. STAAR addressed the questions and issues raised by the Form 483 in its responses provided to the FDA in November 2004 and February 2005.

On July 5, 2005 STAAR received a letter from the FDA stating, among other things, that STAAR's earlier responses reveal that it has "failed to adequately correct numerous violations" noted on the Form 483. The FDA letter goes on to state that the "FDA is gravely concerned about Staar's serious, continuing violations and is prepared to seek the appropriate remedies under the Act." The FDA also indicates that this letter is its final attempt to notify STAAR of its non-compliance and gives STAAR ten calendar days from receipt of the letter to provide its responses and supporting documentation.

STAAR takes all communications from the FDA seriously and intends to respond promptly to this letter. While STAAR cannot predict the FDA's reaction to STAAR's response, STAAR believes that the FDA will pursue enforcement action against STAAR if it finds the response to be inadequate in any material respect. This action, if taken, would most likely have a material and adverse impact on STAAR and its prospects.

STAAR believes that the FDA is unlikely to approve marketing of the VISIAN® ICL in the United States 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. In addition, enforcement or other proceedings may restrict STAAR's established domestic lines of business.

STAAR's response to the FDA's letter will include, among other things, data gathered by STAAR and information about corrective actions taken by STAAR following the 2004 inspection. There can be no assurance that STAAR's responses to the most recent letter will resolve all of the open issues to the FDA's satisfaction, although STAAR is committed to use all efforts to achieve that result. Even if the FDA does accept STAAR's corrective action, the FDA may initiate future or additional actions and has specifically reserved the right to do so in its most recent letter.

Item 9.01 Financial Statements and Exhibits.

Exhibit
Number Description of Exhibit
99.1 Press release dated July 11, 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 11, 2005

By: /s/David Bailey

Name: David Bailey
Title: Chief Executive Officer

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Exhibit Index

Exhibit No.	Description
99.1	Press Release dated July 11, 2005.