STAAR SURGICAL CO
Form 8-K/A
July 29, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K/A

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 28, 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 28, 2005, the Company published a press release related to a letter received from the the Office of Device Evaluation of the U.S. Food and Drug Administration (the "FDA"). A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 8.01 Other Events.

On July 28, 2005, STAAR Surgical Company (the "Company") received a letter from the FDA Office of Device Evaluation stating that the FDA has reviewed the Company's pre-market approval application ("PMA") for the STAAR Myopic VISIAN ICL(TM) and has determined that the PMA 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.

The ICL is a refractive phakic implant intended for placement in the posterior chamber of the eye. The models of the STAAR Myopic Visian ICL(TM) subject to the PMA are indicated for the correction of myopia in adults with myopia ranging from -3.0 to -15.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane and the reduction of myopia in adults with myopia ranging from greater than -15.0 to -20.0 diopters with astigmatism less than or equal to 2.5 diopters at the spectacle plane, in patients 21-45 years of age with anterior chamber depth (ACD) 3.00 mm or greater, and a stable refractive history within 0.5 diopters for one year prior to implantation.

A copy of the letter from the FDA Office of Device Evaluation is attached to this report as Exhibit 99.2 and is incorporated herein by this reference.

As previously reported, on July 5, 2005, the Company received a letter from the FDA informing the Company that it had failed to adequately address observations made at the conclusion of the FDA’s most recent audit of the Company's Monrovia facility on September 23, 2004, and that based on the Company’s responses made by letter in November 2004 and February 2005 the Company was in violation of the FDA’s Quality Systems Regulation and Medical Device Reporting regulations. The Company responded to the letter on July 15, 2005. The Company cannot predict the timing or substance of the FDA’s reaction to the Company's response, but believes that the FDA will pursue enforcement action against the Company if it finds the response inadequate. This action, if taken, would most likely have a material and adverse impact upon the Company and its prospects. The Company continues to believe that the FDA will not grant the Company final approval to market the VISIAN(TM) ICL in the United States until all compliance issues have been resolved.

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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 28, 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 28, 2005.
99.2	Letter from U.S. Food and Drug Administration Office of Device Evaluation dated July 28, 2005.