STAAR SURGICAL CO
Form 8-K
November 23, 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): November 18, 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 November 18, 2005, in response to a request by STAAR Surgical Company ("STAAR"), STAAR received from the U.S. Food and Drug Administration ("FDA") certificates that may be provided to foreign governments (the "Certificates") to permit the importation into foreign countries of STAAR products manufactured at its facility in Monrovia, California. In the Certificates, the FDA certifies that during the FDA's last inspection STAAR's Monrovia manufacturing facility appeared to be in substantial compliance with current good manufacturing practice requirements for the products listed on the Certificates. The listed products include all of the products currently manufactured and sold in the U.S. by STAAR.

A copy of the text of each Certificate is attached to this Report as Exhibit 99.1, and is incorporated herein by this reference.

The Certificates do not relate to the U.S. approval of the Company's VISIAN™ ICL. As the Company previously announced, it received a letter from the FDA on July 28, 2005, stating that the premarket approval application ("PMA") for the Company's 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. Issuance of final approval of the VISIAN ICL remains subject to the further actions of the FDA Office of Device Evaluation.

Forward Looking Statements
All statements in this report that are not statements of historical fact are forward-looking statements, including any statement about the FDA's approval of the Company's PMA for the VISIAN ICL. 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 proceedings of the FDA Office of Device Evaluation, which shall determine whether and when the VISIAN ICL is approved for use in the U.S., and the Company's ability to demonstrate continuous improvement of its quality systems and strict compliance with FDA regulations. Any material failure by the Company to do so in the future could result in damage to the Company's reputation or enforcement action by the FDA, which could restrict the Company's ability to continue its business. 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.

By furnishing the information in this Item 7.01 of this Current Report, the registrant does not represent that such disclosure is required by Regulation FD or that the it contains material investor information that is not otherwise publicly available.

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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

November 23, 2005

By: /s/ David Bailey

Name: David Bailey
Title: President and Chief Executive Officer

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Exhibit Index

Exhibit No.	Description
99.1	FDA Certificate to Foreign Government