

STAAR SURGICAL CO
Form 8-K
December 27, 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):

December 22, 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 December 23, 2005, STAAR Surgical Company (the "Company") published a press release announcing that it had received a letter from the Office of Device Evaluation of the U.S. Food and Drug Administration (the "FDA") on December 22, 2005 (the "Approval Letter") approving the Company's pre-market approval application ("PMA") for the STAAR Myopic VISIAN ICL™. A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 8.01 Other Events.

The Company received the Approval Letter regarding the STAAR Myopic VISIAN ICL™ from the FDA on December 22, 2005.

The ICL is a refractive phakic implant intended for placement in the posterior chamber of the eye. The approved models are indicated for the correction of myopia in adults with myopia ranging from -3.0 to less than or equal 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) of 3.00 mm or greater, and a stable refractive history within 0.5 diopters for one year prior to implantation.

The foregoing summary is qualified in its entirety by reference to the complete text of the Approval Letter, a copy of which is attached to this report as Exhibit 99.2, and which is incorporated herein by this reference.

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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

December 23, 2005

By: *David Bailey*

Name: David Bailey

Title: President and Chief Executive Officer

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Exhibit Index

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press release dated December 23, 2005. |
| 99.2 | Letter from U.S. Food and Drug Administration dated December 22, 2004 regarding approval of Premarket Approval Application for the STAAR VISIAN(TM) ICL. |