STAAR SURGICAL CO
Form 8-K
June 27, 2006

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): June 26, 2006

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.

The Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA) has determined that STAAR Surgical Company's supplemental premarket approval application (PMA) for its Visian® Toric Implantable Collamer® Lens (TICL™) is suitable for filing. The PMA is deemed to have been filed on May 8, 2006. STAAR received notice of CDRH's determination by letter on June 26, 2006.

The Visian TICL is a refractive phakic implant designed for placement in the posterior chamber of the eye to treat both myopia and astigmatism. It is a toric variant of STAAR's Visian ICL™, which was approved by the FDA for the treatment of myopia in 2005.

CDRH's decision to file the PMA is based on an initial review and a threshold determination that the application is complete. CDRH cautions that this action does not imply that it has either performed an in-depth evaluation of the safety and effectiveness of the device or made a decision about the approvability of the application. CDRH has not yet decided whether it is necessary to conduct a public meeting of its ophthalmic devices panel to review the PMA.

The PMA supports an indication for the correction of myopia in adults with myopia ranging from -3.0 to less than or equal to -20.0 diopters, with astigmatism ranging from 1 diopter to 4 diopters at the spectacle plane, with anterior chamber depth of 3.00 mm or greater, and a stable refractive history within 0.5 diopter for one year prior to implantation.

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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

June 27, 2006

By: /s/ Charles Kaufman

Name: Charles Kaufman
Title: Vice President and General Counsel