

STAAR SURGICAL COMPANY
Form 8-K
May 06, 2004

**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): April 29, 2004

STAAR SURGICAL COMPANY

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

0-11634
(Commission File Number)

95-3797439
(IRS Employer Identification No.)

1911 Walker Avenue
Monrovia, California 91016
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (626) 303-7902

Item 5. Other Events and Regulation FD Disclosure.

Our operations are subject to periodic inspection by the U.S. Food and Drug Administration (the "FDA"). Such inspection may result in the FDA ordering changes in our business practices, which changes could be costly for the Company and have a material adverse effect on our business and results of operations.

On December 29, 2003, the Company received a Warning Letter issued by the FDA as a result of an inspection by the FDA's Los Angeles district office in December 2003. A copy of such letter appears as Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 9, 2004. On January 14, 2004, the Company submitted a written response, including the Company's proposed corrective actions. On March 10, 2004, the FDA advised the Company that the Company's plans to address the issues raised in the Warning Letter were

"adequate." On April 23, 2004, the Los Angeles district office of the FDA provided additional guidance concerning certain items in the Company's response and requested additional information. The Company is continuing to complete its corrective actions in response to the initial Warning Letter and to provide the supplemental information requested by the Los Angeles District Office.

On April 26, 2004, the Company received a second Warning Letter from the FDA as a result of four additional issues discovered during the inspection by the Los Angeles district office in December 2003. A copy of the second Warning Letter is attached hereto as Exhibit 99.1. The letter relates to events that occurred from 1997 through 2001 concerning procedures of the Company.

Until the FDA is satisfied with our response, we will not be granted approval to market the ICL in the United States and we may face FDA restrictions on our established domestic lines of business. There can be no assurance the FDA will not issue additional Warning Letters or take other actions related to its December inspection. Even if the FDA approves our corrective action, the publication and receipt of the Warning Letters received by the company or similar actions in the future could harm our reputation and reduce sales.

Item 7. Financial Statements and Exhibits.

(c) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Warning Letter dated April 23, 2004 from the U.S. Food and Drug Administration.
99.2	Press Release dated April 29, 2004.
99.3	Transcript of presentation given by David Bailey and John Bily at a conference call conducted by STAAR Surgical Company on April 29, 2004.

Item 12. Results of Operations and Financial Condition.

On April 29, 2004, STAAR Surgical Company issued a press release announcing financial results for the first fiscal quarter of 2004. A copy is attached as Exhibit 99.2 to this report and is incorporated herein by this reference.

On April 29, 2004, STAAR Surgical Company held an earnings conference call to discuss the financial results for the first fiscal quarter of 2004 ended April 2, 2004. A transcript of the presentation given by David Bailey and John Bily in the call is attached to this report as Exhibit 99.3 and is incorporated herein by this reference.

The information on Item 12 of this Current Report on Form 8-K, including Exhibits 99.2 and 99.3, will not be treated as "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section. This information will not be incorporated by reference into a filing under the Securities Act of 1933, or into another filing under the Exchange Act, unless that filing expressly refers to specific information in Item 12 of this report.

SIGNATURES

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Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report on Form 8-K to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 6, 2004

STAAR SURGICAL COMPANY

By: /s/ John Bily
John Bily
Chief Financial Officer

EXHIBIT INDEX

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