STAAR SURGICAL CO
Form 8-K
May 03, 2019
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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): May 2, 2019

STAAR Surgical Company

(Exact Name of Registrant as Specified in Charter)

Delaware	0-11634	95-3797439
(State or Other Jurisdiction		(IRS Employer
of Incorporation)	(Commission File Number)	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 (see General Instruction A.2. below):

Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1 933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On May 2, 2019, the Company received a letter dated May 2, 2019 from the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA). The FDA advised the Company it had completed an initial scientific review of the Company's premarket approval application (PMA) supplement regarding EVO/EVO+ Visian Implantable Collamer Lens for Myopia and EVO/EVO+ Visian Toric Implantable Collamer Lens for Myopia with Astigmatism. The FDA advised the Company that its PMA supplement lacked information, particularly the clinical evidence and analysis, that would permit the completion of the review and determination of whether there is a reasonable assurance of the device's safety and effectiveness for its intended use. The Company expects to continue discussions with the FDA, including discussing the FDA's concerns with the existing PMA supplement and any new clinical data that may be required.

SIGNATURE

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

May 3, 2019 By:/s/ Caren Mason
Caren Mason
President and Chief Executive Officer