
**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): **October 9, 2015**

SIENTRA, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36709
(Commission
File Number)

20-5551000
(IRS Employer
Identification No.)

420 South Fairview Avenue, Suite 200
Santa Barbara, CA 93117
(Address of Principal Executive Offices and Zip Code)

(805) 562-3500
(Registrant's Telephone Number, Including Area Code)

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 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 8.01. Other Events.

On October 9, 2015, Sientra, Inc. (the “*Company*”) issued a press release announcing that it has sent a letter to plastic surgeons regarding products manufactured by Silimed, one of the Company’s contract manufacturers. A copy of the press release is filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Sientra, Inc. dated October 9, 2015.

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 hereto duly authorized.

SIENTRA, INC.

Dated: October 9, 2015

By: /s/ Hani Zeini
Hani Zeini
President and Chief Executive Officer

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Sientra, Inc. dated October 9, 2015.



Sientra Sends Letter to Plastic Surgeons Regarding Silimed-Manufactured Products

SANTA BARBARA, Calif., October 9, 2015 — Sientra, Inc. (NASDAQ:SIEN), a medical aesthetics company, today announced that it has sent a letter to plastic surgeons regarding products manufactured by Silimed, one of Sientra's contract manufacturers.

Among other things, the letter updates plastic surgeons on actions Sientra is taking:

- Sientra has been in ongoing discussions with the United States Food and Drug Administration (FDA) regarding Brazilian regulatory inquiries into Silimed Products, and is conducting its own review of the matter.
- Out of an abundance of caution, Sientra is voluntarily placing on temporary hold the sale in the United States of all Sientra devices manufactured by Silimed and is also recommending that plastic surgeons discontinue implanting these devices until further notice.
- Brazilian and other regulatory agencies have reiterated that no reports of adverse events and no risks to patient health have been identified in connection with implanting Silimed-manufactured products, and, accordingly, there is no need to explant or adopt any specific procedure or action for those patients who have received them.

The full text of the letter is below:

October 9, 2015

Dear Valued Plastic Surgeon,

As a valued partner to Sientra, we want to ensure we are communicating with you in a timely fashion about the latest information regarding our products.

As we previously announced, we learned that Brazilian regulatory agencies have temporarily suspended the manufacturing of all medical devices made by Silimed, including products manufactured for Sientra, as they continue to review technical compliance issues related to Good Manufacturing Practices (GMP) at Silimed's manufacturing facility.

We have been in ongoing discussions with the United States Food and Drug Administration (FDA) regarding this matter and out of an abundance of caution, we are voluntarily recommending that you temporarily discontinue implanting all Sientra devices manufactured by Silimed. We are also voluntarily placing on temporary hold, the sale in the United States of all Sientra devices manufactured by Silimed, and we ask that you set aside all such devices in a secure location and not use them until further notice.



Let me emphasize that we are taking these steps as a precautionary measure. It is important to note that no reports of adverse events and no risks to patient health have been identified in connection with implanting these Silimed-manufactured products. Furthermore, neither Brazilian regulatory agencies nor any other regulatory authority has found that there is a need to explant these devices or adopt any specific procedure or action for patients who have received them. This finding has been reiterated by the foreign regulators reviewing this matter in their public announcements.

In the meantime, you can continue to reassure your patients as needed by informing them that there has been no indication that these issues would pose a threat to their safety. Furthermore, you should continue to advise your patients who have received Sientra implants to contact you if they experience any complications, consistent with standard patient follow up.

We value the relationships we have built with you, and the safety of your patients is of the utmost importance to us. We are providing this update to ensure that you have all the relevant facts about the steps we are taking now and are committed to taking moving forward. In addition to our discussions with the FDA, we are conducting our own review of this matter. Once we have completed our review, we will make sure you are apprised of any pertinent, additional information. Rest assured that this is a top priority for our company and we are committed to completing our review expeditiously, but thoroughly.

In addition to reaching out to you directly, we will also be posting updates to our website, www.sientra.com. As always, I am available along with my team to address your needs and inquiries. Please do not hesitate to contact us via our information request line at info@sientra.com, or by calling us at 888.708.0808.

Thank you for your patience, understanding and support throughout this process.

Respectfully,

Hani Zeini
Founder and Chief Executive Officer
Sientra, Inc.



About Sientra

Headquartered in Santa Barbara, California, Sientra is a medical aesthetics company committed to making a difference in patients' lives by enhancing their body image, growing their self-esteem and restoring their confidence. The Company was founded to provide greater choice to board-certified plastic surgeons and patients in need of medical aesthetics products. The Company has developed a broad portfolio of products with technologically differentiated characteristics, supported by independent laboratory testing and strong clinical trial outcomes. The Company sells its breast implants and breast tissue expanders exclusively to board-certified and board-admissible plastic surgeons and tailors its customer service offerings to their specific needs. The Company also offers a range of other aesthetic and specialty products.

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