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

December 1, 2022

Date of Report (date of earliest event reported)

Cutera, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**000-50644**	**77-0492262**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

3240 Bayshore Blvd.
Brisbane, California 94005
(Address of principal executive offices)

(415) 657-5500
(Registrant's telephone number, including area code)

N/A
(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 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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock ($0.001 par value)	CUTR	The NASDAQ Stock Market, LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 8.01 Other Events.

In 2019, Cutera, Inc. (the "Company") undertook remediation to remove all marketing materials related to gynecological indications, including vaginal rejuvenation, for MyJuliet, a device designed and manufactured by a third party. This followed commitments that the Company had made to the Food and Drug Administration (the "FDA") to cease the promotion of MyJuliet for all vaginal rejuvenation and similar claims. As part of this remediation, the Company requested that the third party 510(k) owner of MyJuliet also stop promoting vaginal procedures on its U.S. website.

The FDA, however, sent a warning letter to the Company, dated November 10, 2022, identifying a vestigial piece of marketing material. A website that was registered to the Company, but hosted and managed by a non-U.S. third party on the Company's behalf, was mistakenly not taken down in 2019. The Company believes that this was an isolated oversight, is taking responsive actions to prevent any such recurrence and believes that the FDA's concerns can be addressed. The Company intends to fully cooperate with the FDA to resolve the warning letter and responded to the warning letter on December 1, 2022.

However, the Company cannot assure that the FDA will find that the Company's responsive actions are appropriate or that they have been adequately implemented. The Company also cannot assure that the FDA will not find other observations or the timing of the resolution of the warning letter. Until the observations of the FDA are corrected, the Company may be subject to additional regulatory action by the FDA.

The Company issued a press release on December 1, 2022, regarding the FDA warning letter. A copy of the press release is attached as Exhibit 99.1 to this report and the information contained therein, is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of Section 18. Furthermore, the information contained in this report, including Exhibit 99.1 attached hereto, shall not be deemed to be incorporated by reference into any registration statement or other document filed pursuant to the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Cutera, Inc. dated as of December 1, 2022.

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, thereunto duly authorized.

CUTERA, INC.

Date: December 1, 2022

/s/ David H. Mowry

David H. Mowry
Chief Executive Officer

Exhibit 99.1

Cutera, Inc. provides response to FDA Inquiry

BRISBANE, Calif., December 1, 2022 -- Cutera, Inc. (Nasdaq: CUTR) (“Cutera” or the “Company”), a leading provider of aesthetic and dermatology solutions, today disclosed that it has provided a response to a recent FDA inquiry.

In 2019, Cutera undertook remediation to remove all marketing materials related to gynecological indications, including vaginal rejuvenation, for a device designed and manufactured by a third party. This followed commitments that Cutera had made to the FDA to cease the promotion of MyJuliet for all vaginal rejuvenation and similar claims. As part of this remediation, Cutera requested that the 510(k) owner of MyJuliet, Asclepion, also stop promoting vaginal procedures on its US website. Moreover, Cutera offered all existing customers a replacement handpiece for skin revitalization along with a notification that vaginal procedures are not cleared by the FDA.

The FDA, however, recently issued a Warning Letter to Cutera identifying a vestigial piece of marketing material that had escaped Cutera’s attention. Regrettably, a website that was registered to Cutera, but hosted and managed by a non-U.S. third party on Cutera’s behalf, was mistakenly not taken down in 2019. Cutera believes that this was an isolated oversight and is taking action to prevent any such recurrence. The site identified by the FDA is no longer active.

Cutera takes the Warning Letter and compliance with all FDA laws and regulations very seriously. Accordingly, Cutera is undertaking a series of additional corrective and preventive actions to ensure that Cutera continues to operate in full compliance with FDA requirements and its own commitments. These actions are identified in Cutera’s response to the FDA. Cutera will continue to work with the FDA until all such actions are complete.

The MyJuliet system is a non-material segment of Cutera’s business. Cutera has not actively promoted this device since 2019. Furthermore, Cutera has not deployed any new devices in more than one year, with fewer than 150 total systems sold in the four years before the cessation of shipments. The revenue associated with servicing the devices with replacement handpieces is immaterial to Cutera.

Cutera intends to accelerate its full exit from this market segment in a manner that supports our customers while being fully compliant with FDA guidance. Cutera is also taking additional steps internally to ensure that similar lapses do not recur.

About Cutera, Inc.

Brisbane, California-based Cutera is a leading provider of aesthetic and dermatology solutions for practitioners worldwide. Since 1998, Cutera has been developing innovative, easy-to-use products that harness the power of science and nature to enable medical practitioners to offer safe and effective treatments to their patients. For more information, call +1-415-657-5500 or 1-888-4CUTERA or visit www.cutera.com.

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Source: Cutera, Inc.