Cutera, Inc. Provides Response to FDA Inquiry

December 1, 2022

BRISBANE, Calif.--(BUSINESS WIRE)--Dec. 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 The site identified by the FDA is no longer active.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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