



## FDA Clears Cutera's AviClear™ Acne Device

March 25, 2022

*AviClear is the First Device Cleared for the Treatment of Mild, Moderate and Severe Acne  
AviClear has been Proven Safe and Effective Through an Extensive Clinical Trial  
Provides Long-term Resolution of Acne Across All Skin Types*

BRISBANE, Calif.--(BUSINESS WIRE)--Mar. 25, 2022-- CUTERA, INC. (Nasdaq: CUTR) ("Cutera" or the "Company"), a leading provider of dermatology solutions, today announced the U.S. Food and Drug Administration's 510(k) clearance of *AviClear*, the first and only energy-based device to receive this designation for the treatment of mild, moderate, and severe acne.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20220317006022/en/>



(Photo: Business Wire)

*AviClear* is a laser treatment that offers a safe, prescription-free solution for acne.<sup>1</sup> In addition to reducing existing acne, clinical trials show that future breakout episodes are shorter, less intense, and more infrequent following the *AviClear* procedure. Further, acne clearance results continue to improve over time, demonstrating the long-term efficacy of this novel treatment. Importantly, no pain mitigation was utilized or required by any clinical study participant.

Acne vulgaris is a nearly universal skin disease, with approximately 50 million North American teens and young adults seeking treatment each year.<sup>2</sup> Overproduction of sebum by the sebaceous glands is one of the leading causes of acne.<sup>3</sup> *AviClear* resolves acne at the source by selectively targeting the sebocytes and suppressing sebum production.

"Existing device treatments for acne are neither long-lasting nor particularly effective," said Jeffrey S. Dover, MD, FRCP, board-certified dermatologist and Cutera advisory board member. "Topical therapies yield temporary results and oral medications present several challenges. *AviClear* offers patients a safe, well-tolerated, drug-free approach with durable results, which significantly shifts the treatment paradigm for acne."

"Physicians and patients have long sought a modern alternative to the acne pills, peels and topicals that have been static for nearly 30 years," said David Mowry, CEO of Cutera. "Developed with extensive physician and patient input, *AviClear* was created to redefine the treatment of acne – all without a prescription."

*AviClear* is expected to be made available to physicians throughout the United States over the course of 2022. Doctors and consumers are encouraged to visit [www.AviClear.com](http://www.AviClear.com) and sign up for updates on product availability and local treatment providers.

### About Cutera, Inc.

Brisbane, California-based Cutera is a leading provider of laser and other energy-based systems for dermatologists and aesthetic practitioners worldwide. Since 1998, Cutera has been developing innovative, easy-to-use products that harness the power of science and nature to enable physicians and other qualified 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](http://www.cutera.com).

### References

1. Data on file, FDA clearance study. Cutera, Inc.
2. <https://jamanetwork.com/journals/jamadermatology/fullarticle/479093>
3. O'Neill AM, Gallo RL. Host-microbiome interactions and recent progress into understanding the biology of acne vulgaris. *Microbiome* 2018;6: 177.

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