



## PRESS RELEASE

### **Damae Medical Receives FDA Clearance for deepLive™**

Marking a Major Milestone in Company's U.S. Market Expansion Plans

**Paris, France - March 4th, 2025** - Damae Medical, developer of innovative imaging devices and artificial intelligence solutions that provide unmatched diagnostic support to dermatologists, proudly announces that its deepLive™ medical device has received 510(k) clearance<sup>1</sup> from the U.S. Food & Drug Administration (FDA).

deepLive™ is a non-invasive imaging tool that provides real-time, three-dimensional visualization of the skin. This cutting-edge technology empowers dermatologists to perform accurate clinical assessments and evaluate tissue health with increased precision.

As an initial step, deepLive™ has been deployed in 5 medical centers across the U.S., under investigational use only, in order to generate U.S. specific clinical data and confirm the imaging performances of its LC-OCT technology on American patients.

"We have accumulated over three years of clinical experience with the system and are highly impressed with its intuitive interface. It allows seamless task delegation to staff and is highly efficient for use in everyday clinical settings," says Dr. Orit Markowitz, MD, founder of OptiSkin Medical in Manhattan, NY, the first U.S. user of the device.

"It provides a solution for patients as no one wants to have a biopsy of their skin if it can be avoided. If you can simply take an image, make a diagnosis and start some type of therapeutic treatment regimen, that would be a better solution for most patients," adds James Grichnik, MD Phd, chair of USF Health's department of dermatology

This FDA clearance marks a significant milestone in Damae Medical's strategy for U.S. expansion. Anaïs Barut, President and Co-Founder of Damae Medical, comments: "The FDA clearance of deepLive™ sets the stage for Damae Medical's U.S. market launch. We plan to focus on dermatology services in hospitals and private skin cancer clinics involved in skin cancer management across the country."

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<sup>1</sup> [FDA Summary of Safety and Effectiveness Data \(SSED\) for K240610 - U.S. Food and Drug Administration.](#)

### **About Damae Medical**

Damae Medical develops innovative imaging devices and AI solutions that provide unparalleled diagnostic assistance to dermatologists.

Since 2014, Damae Medical has integrated advanced LC-OCT (Line-field Confocal Optical Coherence Tomography) imaging and AI into its deepLive™ solution to provide a unique tool.

Validated by over **240 clinical studies**, deepLive™ has proven its accuracy for the diagnosis of basal cell carcinoma (96%) and other conditions such as melanoma, actinic keratoses, and squamous cell carcinomas. **deepLive™ has obtained CE certification and FDA clearance and is used in more than 14 countries worldwide.**

[www.damae-medical.com](http://www.damae-medical.com).

#### **Press contact**

Anne-Sophie Negroni

+33 6 60 54 49 47

anne-sophie@negroni-associes.fr