



Spectral AI Receives FDA De Novo Clearance for DeepView® System for Burn Indication

May 26, 2026

DALLAS, May 26, 2026 (GLOBE NEWSWIRE) -- **Spectral AI, Inc. (Nasdaq: MDAI)** (“**Spectral AI**” or the “**Company**”), an artificial intelligence (AI) company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, today announced that the U.S. Food and Drug Administration (FDA) granted De Novo Classification for its DeepView® System. With this classification, Spectral AI is authorized to commence commercial distribution activities in the United States. The DeepView System is intended for use in burn care in various settings, including burn centers, trauma centers, and emergency departments.

“We are pleased that the FDA has recognized our novel technology. I am grateful for our dedicated team of employees and this milestone represents the culmination of years of hard work. Our ability to obtain FDA De Novo classification is a defining moment in Spectral AI’s history and a validation of our shared vision to bring to market our innovative predictive medical technology that provides a *Day One* diagnostic assessment of a burn wound’s healing potential,” said Vincent Capone, Chief Executive Officer.

“Today we celebrate a watershed moment in the history of Spectral AI,” said Dr. J. Michael DiMaio, Chairman of the Board of Spectral AI. “Adhering to a mantra of *Finance, Focus, and Finish*, we are now positioned to commence commercialization of the DeepView System, which we believe has the potential to redefine the standard of care in the assessment and treatment of burn wounds. We are confident that this pioneering technology will provide value across the healthcare ecosystem by improving patient outcomes and aligning care quality with cost efficiency.”

About the DeepView System

Spectral AI’s DeepView System is a non-invasive, predictive medical device which combines multispectral imaging with a proprietary AI algorithm to assess the healing potential of areas within the burn wounds. The DeepView System provides clinicians with an immediate, data-driven assessment of whether areas within burn wounds are unlikely to heal within 21 days and may require significant medical intervention, enabling earlier and more informed treatment decisions. The image acquisition takes 0.2 seconds, and all image processing and AI model classification takes approximately 20 to 25 seconds. The DeepView System is trained and tested against a proprietary and clinically validated database of over 340 billion pixels of burn wound image data.

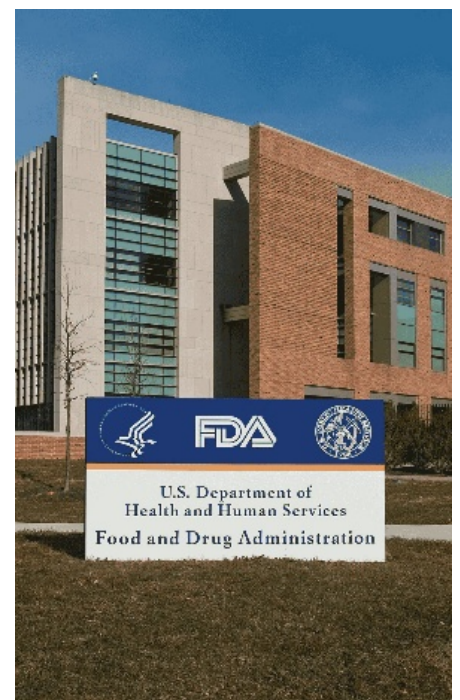
DeepView® System Caption:



Source: Spectral AI



FDA Building





About BARDA and its Support of the DeepView System

This project is being supported in whole or in part with federal funds from the Department of Health and Human Services (DHHS); Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50123C00049. The findings and conclusions have not been formally disseminated by the DHHS and should not be construed to represent any agency determination or policy.

About Spectral AI

Spectral AI, Inc. is a Dallas-based predictive AI company focused on medical diagnostics for faster and more accurate treatment decisions in wound care, with initial applications involving patients with burns. The Company is working to revolutionize the management of wound care by “Seeing the Unknown[®]” with its DeepView System. The DeepView System is being developed as a predictive diagnostic device to offer clinicians an objective and immediate assessment of a burn wound’s healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal of exceeding the current standard of care in the future, the DeepView System is expected to provide fast and accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. Spectral AI has been named to TIME’s list of World’s Top HealthTech companies 2025. For more information about the DeepView System, visit www.spectral-ai.com.

Forward-Looking Statements

Certain statements made in this release are “forward looking statements” within the meaning of the “safe harbor” provisions of the United States Private Securities Litigation Reform Act of 1995, including statements regarding the Company’s strategy, plans, objectives, initiatives and financial outlook. When used in this press release, the words “estimates,” “projected,” “expects,” “anticipates,” “forecasts,” “plans,” “intends,” “believes,” “seeks,” “may,” “will,” “should,” “future,” “propose” and variations of these words or similar expressions (or the negative versions of such words or expressions) are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance, conditions or results, and involve a number of known and unknown risks, uncertainties, assumptions and other important factors, many of which are outside Company’s control, that could cause actual results or outcomes to differ materially from those discussed in the forward-looking statements. As such, readers are cautioned not to place undue reliance on any forward-looking statements.

Investors should carefully consider the foregoing factors, and the other risks and uncertainties described in the “Risk Factors” sections of the Company’s filings with the US Securities and Exchange Commission, including the Company’s Registration Statement and the other documents filed by the Company. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

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