

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 26, 2026

SPECTRALAI, INC.

(Exact name of registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation)	<u>001-40058</u> (Commission File Number)	<u>85-3987148</u> (I.R.S. Employer Identification No.)
2515 McKinney Avenue, Suite 1000 Dallas, Texas		75201
(Address of principal executive offices)		(Zip Code)

(972) 499-4934

(Registrant's telephone number, including area code)

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communication 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-commencements 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 Symbols	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	MDAI	The Nasdaq Stock Market LLC
Redeemable Warrants, each whole warrant exercisable for one share of Common Stock, at an exercise price of \$2.75 per share	MDAIW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company 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 7.01. Regulation FD Disclosure.**

On May 26, 2026, the Company issued a press release announcing that the U.S. Food and Drug Administration granted De Novo Classification for its DeepView® System. With this classification, the Company is authorized to commence commercial distribution activities in the United States. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 to this Current Report on Form 8-K, and in Exhibit 99.1 furnished herewith, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by Spectral AI, Inc. on May 26, 2026.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

**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 hereunto duly authorized.

Dated: May 26, 2026

**SPECTRAL AI, INC.**

By: /s/ Vincent S. Capone

Name: Vincent S. Capone

Title: Chief Executive Officer



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

**DALLAS, TX - May 26, 2026 - 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  
Source: Spectral AI



Source: Wikimedia Commons

### **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<sup>®</sup>” 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](http://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.

### **Investors:**

#### **The Equity Group**

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