Spectral AI Outlines U.S. Regulatory Pathway for DeepView® System for Burn Indication

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DALLAS, Sept. 17, 2024 (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 provided an outline of its regulatory pathway strategy to enter the U.S. market with its flagship DeepView® System for burn indication ("DeepView AI®-Burn").

DeepView AI®-Burn, which received Breakthrough Device Designation from the U.S. Food and Drug Administration ("FDA") in 2018, is a predictive medical device that assesses the healing potential of burns by combining multi-spectral imaging with an AI-driven algorithm trained and tested against a proprietary database of more than 340 billion clinically validated data points. By distinguishing between healing and non-healing tissue, the DeepView® System provides an immediate and binary prediction of wound healing that can support clinical decision-making regarding next step treatment plans.

"We have entered an exciting phase at Spectral AI with the recently announced completion of adult and pediatric patient enrollment at U.S. burn centers for our U.S. Burn Pivotal Study," said Trudy Estridge, Sr. Director of Regulatory Affairs at Spectral AI. "The unique characteristics of DeepView AI®-Burn meet criteria that, to our knowledge, no approved or cleared alternatives registered by the FDA currently possess. Therefore, the Company has decided to pursue a De Novo submission requesting classification of DeepView AI®-Burn as a Class II medical device. This process provides a pathway for FDA clearance for low- or medium-risk medical devices with no existing predicate, or no substantial equivalence. We expect to submit this request in the second quarter of 2025 and, if granted, the FDA will create a new product code for the DeepView® System."

DeepView AI®-Burn was previously granted Breakthrough Device Designation by meeting two key criteria determined by the FDA. First, the Device provides for a more effective treatment or diagnosis relative to the current standard of care in the U.S. Second, the Device represents a novel technology that has the potential to lead to a clinical improvement in the diagnosis, treatment, cure, mitigation, or prevention of the life-threatening or irreversibly debilitating disease or condition.

"The process of developing an innovative healthcare solution with the potential to change the standard of care is a long and challenging process," said Peter M. Carlson, Chief Executive Officer of Spectral AI. "Our progress to date reflects the commitment of our dedicated team of employees and consultants, government partners, and study participants. I remain exceedingly grateful for their continuing support. As we pursue FDA submission for DeepView AI®-Burn, we are following a process that we believe can capitalize on the platform nature of our DeepView® System and expedite the commercialization of additional pipeline applications. We look forward to our future with confidence."

The DeepView® System wound healing assessment platform empowers clinicians at all levels with the insights necessary for timely and informed treatment decisions. The use of the DeepView® System aims to deliver expedited treatment, reduce potential complications, improve patient outcomes, and more efficiently allocate limited healthcare resources.

For more information on the FDA De Novo process and Breakthrough Device program, visit:
BreakthroughDevicesProgram@fda.hhs.gov
https://www.nature.com/articles/s41746-024-01021-y
https://medicaldeviceacademy.com/de-novo-review-timeline/
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm

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 and diabetic foot ulcers. The Company is working to revolutionize the management of wound care by "Seeing the Unknown ®" with its DeepView ® System. The DeepView® System is a predictive device that offers clinicians an objective and immediate assessment of a wound's healing potential prior to treatment or other medical intervention. With algorithm-driven results and a goal to change the current standard of care, the DeepView® System is expected to provide faster and more accurate treatment insight towards value care by improving patient outcomes and reducing healthcare costs. 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 SEC, including the 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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