

Spectral Submits Application for UKCA Mark Classification

Jan 29, 2024

DALLAS, Jan. 29, 2024 (GLOBE NEWSWIRE) -- Spectral MD, Inc. ("SMD"), a subsidiary of Spectral AI, Inc. (NASD: MDAI; MDAIW) ("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 the submission of an application in the United Kingdom for its predictive software DeepView AI[®]-Burn to be registered as UK Conformity Assessed (UKCA) for burn wound use in the UK.

"We are pleased to reach this milestone towards the initial commercialization opportunity for our DeepView AI [®]-Burn algorithm, which contains our first AI software release that can be used for assessment and management of thermal burn wounds," said Niko Pagoulatos, Ph.D., Chief Operating Officer of Spectral AI. "We look forward to hearing about our application in the first half of 2024."

There is currently no diagnostic tool in the market to be used for burn wounds, and early and reliable assessment of burn severity is critical for better management of burn patients. The predictive software DeepView Al[®]-Burn seamlessly integrates with our UKCA granted application for our imaging device, DeepViewSnapShot.[®] The DeepView System processes the image and displays the original wound, while highlighting the nonhealing parts of the burn, defined as deep 2nd and 3rd degree burns. This diagnostic predictive analysis is delivered within seconds and aids physicians in making an informed decision on patient treatment protocols.

UKCA marking is a product certification system established by the UK government to ensure that products sold in the UK market (England, Wales, and Scotland) comply with relevant laws and technical standards. The DeepView Al[®]-Burn indication is for individuals aged eighteen years and older. The Company is looking towards expanding its technology to serve pediatric populations and is continuing to initiate case studies and case series with surgeons at leading burn centres.

About Spectral Al

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. DeepView[®] is a predictive diagnostic 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 of substantially exceeding the current standard of care in the future, DeepView[®] 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 DeepView[®], visit <u>www.spectral-ai.com</u>.

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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