Spectral AI's DeepView SnapShot® Wound Imaging System, Achieves UKCA Mark and FDA Class 1 Medical Device Classification

Oct 19, 2023

DeepView SnapShot® devices shipped to UK burn centers for evaluation

DALLAS, Oct. 19, 2023 (GLOBE NEWSWIRE) -- **Spectral AI, Inc. (Nasdaq: 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 that its DeepView SnapShot® Wound Imaging System (DeepView SnapShot®) is now UK Conformity Assessed (UKCA)-marked for use in the United Kingdom and has received Class 1 medical device classification with the United States Food and Drug Administration (FDA).

"We are thrilled to announce the UKCA marking and Class 1 medical device classification from the FDA for our DeepView SnapShot® Wound Imaging System. Spectral AI's commitment to advancing medical diagnostics in tissue health is reflected in these important milestones," said Wensheng Fan, CEO of Spectral AI. "We are confident that our unique AI-driven imaging platform will empower healthcare professionals in making critical decisions around the world, and these regulatory developments are significant steps towards achieving that goal."

UKCA marking is a product certification system launched by the UK government to ensure that products sold in the UK market (England, Wales, and Scotland) comply with the relevant technical standards and requirements. Following this marking, the Company has designated six DeepView SnapShot® devices to be used for evaluation by healthcare professionals in the UK. Furthermore, the DeepView SnapShot® device obtained Class 1 medical device classification from the FDA. The FDA employs a comprehensive classification system to rigorously ensure the safety and effectiveness of medical devices. Within this framework, Class 1 medical devices are specifically categorized for their minimal risk potential to patients and operators.

Now that the Company has received classification for the DeepView SnapShot® imaging device, Spectral AI will seek the regulatory approval for its DeepView AI® - Burn software to commercialize the complete DeepView SnapShot® System in the United States and across the globe.

"The unpredictability of severe burn injuries is a growing and critical problem around the world. We believe that Spectral AI's DeepView ® platform will allow healthcare providers to make more accurate, timely and informed decisions regarding the treatment of these wounds," said Niko Pagoulatos, Chief Operating Officer of Spectral AI. "We are very pleased with these important incremental regulatory developments in the UK and the US as part of our ongoing efforts to commercialize the DeepView® platform."

Spectral AI's DeepView SnapShot® is a patented, universal imaging platform that can house multiple clinical indications and predictive AI software to assist clinicians to make faster, accurate decisions in wound care. DeepView® integrates optical technology and AI-enabled algorithms using a proprietary database of 263 billion clinically validated data points to see deep below the skin's surface and distinguish between healthy and damaged tissue.

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. 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 www.spectral-ai.com.

Forward Looking Statements

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