Hyperfine, Inc. Receives FDA Clearance for Updated AI-powered Software with Improved Image Quality for All Swoop® System Sequences

October 9, 2023

Advanced artificial intelligence (AI) algorithms are now integrated across all Swoop® ultra-low-field brain imaging system sequences

GUILFORD, Conn.--(BUSINESS WIRE)--Oct. 9, 2023-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking medical device company that has redefined brain imaging with the world's first FDA-cleared portable magnetic resonance brain imaging system—the Swoop® system—today announced FDA clearance of updated software. Built on a robust AI foundation, the latest software brings image quality enhancements to the Swoop® system's diffusion-weighted imaging (DWI) sequence.

With this latest software update, Hyperfine, Inc. expands the Swoop® system's AI denoising capabilities by incorporating advanced image post-processing into the DWI sequence. The system's other sequences (T1, T2, and FLAIR) previously benefited from this AI feature. Denoising enables a crisper image that potentially helps clinicians more accurately diagnose, treat, and monitor patients undergoing brain imaging.

"We believe in making brain imaging more accessible, clinically relevant, and actionable. We continue to make meaningful progress across all sequences. With this significant and most recent update, we now incorporate deep learning into our DWI sequence," said Tom Teisseyre, chief operating officer of Hyperfine, Inc. "These imaging improvements will serve a critical role in enhancing image quality for healthcare professionals in time-sensitive environments."

Maria Sainz, president and CEO of Hyperfine, Inc., remarked, "Our eighth FDA software clearance in three years for the Swoop® system underscores our relentless drive for innovation and continuous improvement. Our focus remains on providing quality brain imaging to more providers and patients in more sites of care. More than milestones, it's about reshaping patient care, empowering clinicians, and advancing brain imaging."

Hyperfine, Inc. will roll out the updated Swoop® system software in the coming months.

For more information about the Swoop® Portable MR Imaging® System, please visit hyperfine.io.

About Hyperfine, Inc. and the *Swoop*® *Portable MR Imaging*® System

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking medical technology company that has redefined brain imaging with the Swoop® system—the world's first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of care. The *Swoop*® system received initial U.S. Food and Drug Administration (FDA) clearance in 2020 as a portable magnetic resonance brain imaging device for producing images that display the internal structure of the head where a full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis. The *Swoop*® system has been approved for brain imaging in several countries, including Canada and Australia, has UKCA certification in the United Kingdom, CE certification in the European Union, and is also available in New Zealand.

The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging and data solutions. Founded by Dr. Jonathan Rothberg in a technology-based incubator called 4Catalyzer, Hyperfine, Inc. scientists, engineers, and physicists developed the *Swoop*® system out of a passion for redefining brain imaging methodology and how clinicians can apply accessible diagnostic imaging to patient care. Traditionally, access to costly, stationary, conventional MRI technology can be inconvenient or not available when needed most. With the portable, ultra-low-field *Swoop*® system, Hyperfine, Inc. is redefining the neuroimaging workflow by bringing brain imaging to the patient's bedside. For more information, visit hyperfine.io.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Actual results of Hyperfine, Inc. (the "Company") may differ from its expectations, estimates and projections and consequently, you should not rely on these forward-looking statements as predictions of future events. Words such as "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "could," "should," "believes," "predicts," "potential," "continue," and similar expressions (or the negative versions of such words or expressions) are intended to identify such forward-looking statements. These forward-looking statements include, without limitation, the Company's goals and commercial plans, the benefits of the Company's products and services, and the Company's future performance and its ability to implement its strategy. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside of the Company's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: the success, cost and timing of the Company's product development and commercialization activities, including the degree that the *Swoop*® system is accepted and used by healthcare professionals; the impact of COVID-19 on the Company's business; the inability to maintain the listing of the Company's Class A common stock on the Nasdaq; the Company's inability to grow and manage growth profitably and retain its key employees; changes in applicable laws or regulations; the inability of the Company to raise financing in the future; the inability of the Company to obtain and maintain regulatory clearance or approval for its products, and any related restrictions and limitations of any cleared or approved product; the inability of the Company to identify, in-license or acquire additional technology; the inability of the Company to maintain its existing or future license, manufacturing, supply and distribution agreements and to obtain adequate supply of its products; the inability of the Company to compete with other companies currently marketing or engaged in the development of products and services that the Company is currently marketing or developing; the size and growth potential of the markets for the Company's products and services, and its ability to serve those markets, either alone or in partnership with others; the pricing of the Company's products and services and reimbursement for medical procedures conducted using the Company's products and services; the Company's estimates regarding expenses, revenue, capital requirements and needs for additional financing; the Company's financial performance; and other risks and uncertainties indicated from time to time in Company's filings with the

Securities and Exchange Commission, including those under “Risk Factors” therein. The Company cautions readers that the foregoing list of factors is not exclusive and that readers should not place undue reliance upon any forward-looking statements, which speak only as of the date made. The Company does not undertake or accept any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or any change in events, conditions or circumstances on which any such statement is based.

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