Hyperfine Announces FDA Clearance of Software Update That Enables Faster Acquisition of Best-in-Class Ultra-Low-Field Brain Images

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The total number of Hyperfine AI-powered marketing authorizations places the company in a leading position on recently published FDA list.

GUILFORD, Conn.--(BUSINESS WIRE)--Jul. 17, 2024-- Hyperfine (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 the clearance of the ninth generation of AI-powered Swoop® system software. This advanced software significantly reduces scan times across multiple MR sequences without sacrificing image quality. The U.S. Food and Drug Administration (FDA) clearance of this software further solidifies Hyperfine as a leader in AI-powered health technology.

These scan time reductions may enable Swoop® system images to help speed up the diagnostic process in acute care settings, which is crucial for time-sensitive medical conditions such as stroke, where every second counts. Reducing the overall acquisition time for sequences can also decrease the negative impact of patient motion on image quality.

Professor Adnan Siddiqui, MD, PhD, from the University of Buffalo, emphasized the impact of rapid imaging capabilities, saying, "Timely MR brain imaging is essential for clinicians making critical treatment decisions, particularly in acute neurological episodes like strokes. We have been an active site in the ACTION PMR study assessing the use of the Swoop® system in stroke diagnosis, and this latest software will help the Swoop® system more seamlessly integrate into stroke workflows. It is wonderful to see Hyperfine respond quickly to clinical feedback and continue to innovate to improve the Swoop® system."

The total number of Hyperfine AI-powered marketing authorizations places the company in a leading position on the FDA's Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices[1] list, underscoring the commitment of Hyperfine to leveraging AI to advance ultra-low-field portable MR brain imaging technology and improve patient care.

"With the release of our ninth-generation AI-powered software, we continue to broaden the clinical utility and workflow fit of the Swoop® system," said Tom Teisseyre, Chief Operating Officer at Hyperfine. "The balance between speed and image quality is crucial in acute care settings where early and timely information is essential to inform the best decisions for patients. We're proud of every step we've taken with the Swoop® system, learning from and responding to our user base and the broader medical community."

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

About the Swoop® Portable MR Imaging® System

The Swoop® Portable MR Imaging® system is U.S. Food and Drug Administration (FDA) cleared for brain imaging of patients of all ages. It is a portable, ultra-low-field magnetic resonance imaging device for producing images that display the internal structure of the head where 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 also has CE certification in the European Union and UKCA certification in the United Kingdom. The Swoop® system is commercially available in a select number of international markets.

About Hyperfine, Inc.

Hyperfine, Inc. (Nasdaq: HYPR) is the groundbreaking health technology company that has redefined brain imaging with the Swoop® system—the first FDA-cleared, portable, ultra-low-field, magnetic resonance brain imaging system capable of providing imaging at multiple points of care. The mission of Hyperfine, Inc. is to revolutionize patient care globally through transformational, accessible, clinically relevant diagnostic imaging. 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. 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.

[1] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

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