Hyperfine Announces FDA Clearance of the Next Optive AI™ Software, Further Enhancing Image Quality, Clinical Utility, and Ease of Use of the Swoop® System Across Care Settings

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This newest software delivers improved image quality across Swoop system sequences, a more intuitive scanning experience, and new foundational isotropic imaging designed to strengthen the clinical utility of portable MRI.

GUILFORD, Conn.--(BUSINESS WIRE)--Aug. 20, 2026-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared AI-powered portable MRI system for the brain—the Swoop® system—today announced that it has received FDA clearance for its latest Optive AI™ software update. This advancement is Hyperfine's second FDA-cleared software package since the launch of its next-generation Swoop system in mid-2025. It builds on Hyperfine's Optive AI software to deliver even higher image quality in challenging clinical environments, a more intuitive scanning experience for Swoop system operators, and a new imaging sequence for three-dimensional visualization—further extending the clinical value of the Swoop system across care settings.

Since the Swoop system does not require the shielding that conventional high-field MRI systems depend on, it can scan in electromagnetically noisy environments, such as intensive care units and emergency departments, without sacrificing image quality. This latest advancement in Optive AI software takes Hyperfine's proprietary noise cancellation a step further, improving noise correction across all sequences to deliver clearer, more consistent images that move closer to high-field quality, even in noisy point-of-care environments where only the Swoop system can go. The software also introduces an improved user interface with a more guided scanning workflow and lets operators view sequences and images as they're being acquired, making the system even more intuitive and easier to use.

This latest update debuts the isotropic T1 sequence, delivering thinner slices and equally high resolution across all imaging planes. This new capability is especially valuable in clinical situations where spatial visualization supports clinical assessment, such as post-operative tumor follow-up, and represents a new brain imaging capability now possible in the ultra-low field Swoop system.

"This latest advancement reflects our commitment to frequent Optive AI software updates that continuously expand the clinical value of the Swoop system and provide our customers with access to the most advanced portable brain MRI technology available," said Tom Teisseyre, Chief Operating Officer of Hyperfine. "This software is designed to improve performance today and is also architected for our ultra-low-field future. Capabilities such as the new isotropic T1 sequence are particularly exciting because they demonstrate just how clinically valuable imaging at this field strength can be. We've also established a foundation for future potential applications such as neurosurgery contrast imaging and quantitative MRI, opening the door to additional sites of care for the Swoop system."

Hyperfine plans to start the rollout of this new software in the United States to existing and new Swoop system users in September.

For more information about the Swoop system, please visit HyperfineMRI.com.

About the Swoop® Portable MRI Systems
The Swoop® Portable MR Imaging® Systems are U.S. Food and Drug Administration (FDA) cleared for brain imaging of patients of all ages. They are portable, ultra-low-field magnetic resonance imaging devices 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.

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 professional 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 HyperfineMRI.com.

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, including its entrance into new markets. 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 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 progress on product advancements and improvements ; 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; existing and potential future National Institutes of Health funding pressures; existing and potential future effects from U.S. export controls and tariffs; 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 the 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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