# Hyperfine Receives CE Mark and UKCA Approval for Optive AI™ Software, Expanding Global Commercialization of Latest AI-Powered Imaging Software

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*Approvals mark a major milestone and bring the most advanced image quality to date to Swoop® system users in European markets*

GUILFORD, Conn.--(BUSINESS WIRE)--Sep. 2, 2025-- 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 it has received CE Marking and UK Conformity Assessment (UKCA) approval for its Optive AI™ software. These approvals, which closely follow the US FDA clearance, deliver a substantial leap in image quality for the Swoop® portable MRI system and expand international access to the latest Hyperfine AI-powered imaging software. Together, they mark a pivotal step in the company's ongoing commercial expansion across international markets.

Optive AI™ software enhances each stage of the imaging process—from noise cancellation and image acquisition to reconstruction and post-processing. The result is brain images with greater clarity, uniformity, and sharper anatomical detail. The software is fully compatible with first-generation Swoop® systems and requires no hardware modifications, enabling current users to benefit from the dramatic AI-driven image quality enhancements.

"In L'Aquila, over the last few months, we have been leading a project with two other Italian centers to use the Swoop system for stroke triage. The new Optive AI™ software, with the latest AI from Hyperfine, provides a very significant upgrade in image quality and opens additional opportunities to deploy the Swoop® system clinically for easier and more efficient access to MRI in healthcare systems," said Professor Simona Sacco, Head of Neurology at the University of L'Aquila.

Multiple sites across European markets are already using the Swoop® system to support patient care in pediatric, critical care, stroke, and neurodegenerative settings. Hyperfine will begin deploying Optive AI™ software to current Swoop® system users in the European Economic Area (EEA) and UK in the fourth quarter of 2025, with local language support available at launch.

"Our research with the Swoop® system thus far aims to develop a more accessible approach to dementia assessment. Furthermore, we are planning to deploy the portable scanner to improve efficiency and reach of MRI in Kent. The introduction of Optive AI™ software provides a dramatic improvement in image quality, and we are excited about the opportunities for portable brain MRI with the Swoop® system across the UK," added Dr. Joanne Rodda, consultant psychiatrist and researcher at Kent and Medway NHS Trust and Social Care Partnership Trust.

"Optive AI™ software delivers a substantial improvement in image quality, which improves diagnostic confidence and enables broader use in a variety of clinical settings. We are excited to bring these advancements to clinicians and patients in the EEA and UK to drive global adoption of our Swoop® system," said Maria Sainz, President and Chief Executive Officer of Hyperfine, Inc. "These approvals underscore our commitment to operational excellence and global expansion, and achieving them so quickly after our US FDA clearance is a testament to the strength of our regulatory and product teams."

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.

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**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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