Hyperfine Receives CE and UKCA Marks for Next-Generation Swoop® System and Latest Advancement in Optive AI™ Software

April 9, 2026

This milestone unlocks Hyperfine's most significant technology innovations to date for clinicians and patients across Europe and the United Kingdom, delivering a transformative leap in image quality and a major expansion of clinical capability for European markets

GUILFORD, Conn.--(BUSINESS WIRE)--Apr. 9, 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 it has received CE Marking and UK Conformity Assessment (UKCA) approval for both the next-generation Swoop® system and the latest advancement in its Optive AI™ software. Together, these regulatory approvals enable commercialization of Hyperfine's most advanced portable MRI technology across Europe and the United Kingdom (UK), expanding access to high-quality brain imaging at the point of care and representing a pivotal milestone in the company's international commercial growth strategy.

The next-generation Swoop® scanner, which was cleared by the FDA in the second quarter of 2025, represents a significant advancement in portable brain MRI, delivering substantial improvements in image quality, workflow, and overall user experience. The next-generation Swoop® system has generated strong customer interest in the US market, where Hyperfine has placed systems in critical care and emergency rooms of hospitals, as well as in neurology offices.

In addition, Hyperfine received European approvals for the latest advancement in its Optive AI™ software, which was cleared by the FDA in December 2025. The new software includes a new multi-direction diffusion-weighted imaging (DWI) sequence that acquires and averages images from multiple diffusion directions, similar to the method used in high-field MRI scanners. This capability produces cleaner, more consistent images that are especially valuable for stroke diagnosis, enabling better detection of small strokes and enhancing the value of the Swoop® system in acute neurological care. The software is part of the next-generation Swoop® system and is also available as a standalone software upgrade, so existing users benefit from the same powerful imaging platform.

These approvals cover markets across the European Economic Area and the United Kingdom, representing a significant global healthcare market opportunity. The Swoop® system is currently commercialized in these markets through a strong network of distributors across over a dozen countries.

"We are proud to bring our most innovative technology to clinicians and patients in Europe and the UK and are thrilled to have achieved these approvals ahead of our internal expectations," said Maria Sainz, President and CEO of Hyperfine. "This milestone is a testament to the exceptional execution of our product and regulatory teams and meaningfully advances a key pillar of Hyperfine's 2026 international growth strategy. We believe that the next-generation Swoop® system will accelerate international adoption of our technology and strengthen our position as the global leader in AI-powered portable brain imaging."

Hyperfine plans to initiate commercialization of the next-generation Swoop® system and the latest Optive AI™ software in Europe and the UK early in the third quarter of 2026.

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 inability to maintain the listing of the Company's Class A common stock on the Nasdaq Stock Market; 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; anticipated National Institutes of Health funding pressures; the effect of 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260409030745/en/

Media Contact
Devin Zell
Hyperfine
dzell@hyperfine.io

Investor Contact
Webb Campbell
Gilmartin Group LLC
webb@gilmartinir.com

Source: Hyperfine, Inc.