Hyperfine Announces Regulatory Approval of the Swoop® System in India

December 17, 2025

India's Central Drugs Standard Control Organization (CDSCO) has approved the Hyperfine Swoop system, opening a major global market. Commercial launch to begin early 2026.

GUILFORD, Conn.--(BUSINESS WIRE)--Dec. 17, 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 the Swoop® system has received regulatory approval in India from the Central Drugs Standard Control Organization (CDSCO), opening access to advanced brain imaging in one of the world's largest and fastest-growing healthcare markets with a significant unmet need.

The CDSCO approval authorizes the commercialization of the Swoop® portable MRI system throughout India. Hyperfine will distribute the Swoop® system in partnership with Radiosurgery Global, Ltd. (RSG), a leading medical device distributor with expertise in advanced medical imaging and an established network across India's healthcare system.

“The partnership between Hyperfine and RSG will enable us to transform a vision into reality. This partnership unites Hyperfine’s transformative portable brain MRI technology with RSG’s deep market access, regulatory fluency, and operational discipline in India,” said Kapil Kalra, Managing Director, Radiosurgery Global, Ltd. “This collaboration addresses India’s unmet need for accessible brain imaging while establishing a scalable pathway for sustained adoption of portable MRI throughout the healthcare system—transforming how and where neurological imaging is delivered across the country.”

India represents one of the most significant global opportunities for improved access to neuroimaging. Despite a population exceeding 1.4 billion, the country has a comparatively limited base of MRI systems, with far fewer high-field scanners per capita than most developed nations. The high cost and complex infrastructure requirements of conventional MRI systems have historically prevented widespread adoption across India's diverse healthcare landscape. Many patients—particularly those in remote or lower-resource settings—face long travel times to reach hospitals with MRI suites and prohibitive imaging costs, contributing to delayed diagnosis and limiting access to advanced neurological care.

“With portability, low infrastructure requirements, and affordability relative to conventional MRI, the Swoop® system is particularly well-suited for India's diverse healthcare landscape,” said Maria Sainz, President and Chief Executive Officer of Hyperfine, Inc. “From major urban hospitals to remote community health centers, the Swoop® system expands both geographic and economic access to brain imaging—helping providers deliver timely assessment for conditions such as stroke, traumatic brain injury, and neurodegenerative conditions.”

She continued, “This regulatory approval further advances our global expansion strategy and reinforces the value and opportunity of bringing brain imaging directly to patients worldwide.”

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.

The Hyperfine logo, Swoop, and Portable MR Imaging are registered trademarks of Hyperfine, Inc. The Swoop logo, Optive AI logo, and Optive AI are trademarks of Hyperfine, Inc.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20251217651757/en/

Media Contact
Devin Zell
Hyperfine
dzell@hyperfine.io

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

Source: Hyperfine, Inc.