Hyperfine Swoop® Portable MR Brain Imaging System Meets New Standards Recently Issued by CMS-Approved Accrediting Body

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Intersocietal Accreditation Commission (IAC)'s release of new standards accepting ultra-low-field MRI technology enables accredited facilities to qualify for reimbursement from the US Centers for Medicare & Medicaid Services (CMS).

GUILFORD, Conn.--(BUSINESS WIRE)--Nov. 21, 2024-- Hyperfine, Inc. (Nasdaq: HYPR), the groundbreaking health technology company that has redefined brain imaging with the first FDA-cleared portable magnetic resonance (MR) brain imaging system—the Swoop® system—today announced the issuance of new MRI standards by the Intersocietal Accreditation Commission (IAC), a leading CMS-approved accrediting body. The new standards, effective immediately, now include portable MR scanning at the point of care.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20241121507397/en/



The Swoop® Portable MR Imaging® System (Photo: Business Wire)

The IAC, a nonprofit accrediting organization dedicated to quality improvement and patient safety, has updated its advanced imaging standards to incorporate ultra-low-field MRI technology. The updated *IAC Standards and Guidelines for MRI Accreditation* addresses new technology that allows point-of-care service for MRI brain exams. This change enables IAC-accredited facilities and medical offices in the US to qualify for CMS reimbursement for brain scans performed using the Swoop® system.

The compact and versatile Swoop® Portable MR Imaging® system is designed for use in any professional healthcare setting, including medical offices. Its ultra-low field strength of 0.064T eliminates the need for costly shielded MRI rooms. Its plug-and-scan functionality and user-friendly tablet interface enable medical staff to easily operate the system.

"The new IAC guidelines, which outline personnel, training, and safety requirements for MRI accreditation, pave the way for the Swoop® system to be available in neurology offices and clinics," said Maria Sainz, President and CEO of Hyperfine. "With IAC accreditation, physicians can now obtain diagnostic-quality MR brain images within their clinics, providing patients with timely and convenient MRI access at the point of care."

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 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 hyperfine.io.

The Hyperfine logo, Swoop, and Portable MR Imaging are registered 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.

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Media Contact
Dana Schroeder
Health+Commerce
dana@healthandcommerce.com

Investor Contact
Marissa Bych
Gilmartin Group LLC
marissa@gilmartinir.com

Source: Hyperfine, Inc.