Hyperfine Receives 510(k) Clearance from US FDA

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[August 13, 2020: Guilford, CT] Hyperfine, Inc. has received 510(k) clearance from the US FDA for its category-defining portable MRI technology, the Swoop™ Portable MR imaging device. Hyperfine's Swoop™ system is a point-of-care MR imaging device that wheels directly to the patient's bedside, plugs into a standard electrical wall outlet and is controlled through a wireless tablet, making MR imaging accessible, immediate and seamless.

This clearance for the market-ready device covers enhanced imaging and software, and expands Hyperfine's brain imaging indication to include patients aged 0 to 2. Swoop™ is the company's latest-generation device, incorporating user feedback and technological enhancements evolving from the original device, which was cleared in February, 2020. With this clearance, the Swoop™ system is now available for purchase, with shipments commencing immediately.

Magnetic Resonance Imaging uses a magnetic field, radio waves and a computer to produce detailed pictures of the body's internal structures that are clearer, more detailed and more likely in some instances to identify and accurately characterize disease than other imaging methods. However, fixed MRI systems can be inconvenient and inaccessible for providers and patients, particularly when time is critical. Transport to the MR suite demands complicated scheduling coordination, moving patients, and, often, 4 to 6 hour patient backlogs – all which compromise the utility of MRI as a diagnostic tool in time-sensitive settings such as intensive care units and emergency rooms. Furthermore, high capital investments, electrical power needs and significant maintenance requirements present a barrier to adoption across all populations, acutely so for developing countries and rural geographies.

Hyperfine's Swoop™ system was designed to address the limitations of current imaging technologies and make MRI accessible anytime, anywhere, to any patient. Swoop™ wheels directly to the patient's bedside, plugs into a standard electrical wall outlet, and is controlled by a wireless tablet such as an Apple iPad®. Images are captured at the patient's bedside, with results in minutes, enabling critical decision-making capabilities across a variety of clinical settings including neuro intensive care units, emergency departments, pediatrics, ambulatory, outpatient surgery centers and more. The complete Hyperfine system costs less than the annual service contract alone for most current MRI systems, and it consumes 35 times less power than those same systems. Designed as a complementary system to traditional MRIs, new users can be trained on system operation, device navigation and device safety in about 30 minutes, helping clinicians to streamline workflow.

"Six years ago, we had a crazy vision to create a new product category for imaging: an affordable point-of-care MRI system. With this clearance from the FDA, we are launching an astonishing new diagnostic tool for patients and providers in our Swoop™ Portable MRI, and we are delivering on our mission to democratize healthcare across clinical settings and geographies," said Jonathan Rothberg, PhD, founder and chairman of Hyperfine.

About Hyperfine

Hyperfine is on a mission to make MRI accessible to every patient regardless of income or resources, anywhere, anytime. The company's original Portable MRI system received its first US FDA 510(k) clearance in February, 2020 for head imaging of patients 2 years of age and older. Hyperfine is part of 4Catalyzer, a health technology incubator with facilities in Connecticut, New York City, Palo Alto, and Taiwan. www.hyperfine.io.