

US-based Hyperfine receives regulatory approval of Swoop® System in India for brain imaging

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Commercial launch to begin early 2026



US-based Hyperfine, Inc., the groundbreaking health technology company that has redefined brain imaging with the first US FDA-cleared artificial intelligence (AI)-powered portable MRI system for the brain—the Swoop® system—has announced the Swoop® system has received regulatory approval in India from the Central Drugs Standard Control Organisation (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 authorises the commercialisation of the Swoop® portable MRI system throughout India. Hyperfine will distribute the Swoop® system in partnership with Radiosurgery Global (RSG), a leading medical device distributor with expertise in advanced medical imaging and an established network across India's healthcare system.

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.

“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.