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Taiwanese startup Brain Navi achieves US FDA approval for neurosurgical robot NaoTrac

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Paving the way for broader international adoption



Brain Navi Biotechnology, a medical robotics company founded in 2015 in Taiwan by surgeon and serial entrepreneur Jerry Chen, has reached another major milestone.

Following previous approvals from the Taiwan Food and Drug Administration (TFDA) and the CE Mark for Europe, Brain Navi has now received FDA 510(k) clearance for its stereotaxic guiding surgical device, NaoTrac — reinforcing our commitment to innovation, patient safety, and continuous improvement in the neurosurgical field.

For Brain Navi, this is a significant step forward, opening the door to new high-potential markets while affirming the quality and reliability of NaoTrac, its flagship robotic system. This milestone not only expands global footprint but also validates the years of clinical research and development invested in the technology.

The firm has received FDA 510(k) clearance, which confirms that NaoTrac is substantially equivalent in safety and effectiveness to legally marketed devices in the US. This recognition enables the startup to bring NaoTrac to US hospitals and surgical teams, helping them achieve even higher levels of precision and efficiency in the operating room and save more lives.

NaoTrac combines advanced robotic automation with AI-driven accuracy, aiming to elevate neurosurgical outcomes and improve safety for both surgeons and patients.

This step marks a before-and-after moment for Brain Navi — one that paves the way for broader international adoption. As they move forward, the firm expect to see more and more NaoTrac systems installed around the world, supporting surgical teams and improving patient care across borders.