



Sentire® Surgical System Receives CE Mark (MDR) Approval, Cornerstone Robotics Enters a New Era in its Global Expansion

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

HONG KONG, May 25, 2026 /PRNewswire/ - Cornerstone Robotics (CSR), a leading global innovator in surgical robotics based in Hong Kong, China, is pleased to announce its Sentire® Endoscopic Surgical System (hereinafter Sentire® Surgical System) has officially received European Union CE mark certification under the Medical Device Regulation (MDR), covering minimally invasive surgical procedures in General Surgery, Gynecology, Thoracic and Urology. This milestone formally grants the Sentire® Surgical System access to the European markets.

Achieving Combined Regulatory Approval and Clinical Validation

The Sentire® Surgical System is a high-end surgical robotic platform that combines clinical workflows with integrated engineering, software, and imaging technologies. Achieving CE certification affirms that its safety, efficacy, and quality management system fully comply with stringent European regulatory standards and is now positioned to serve physicians and patients worldwide.

The Company established an early presence in the UK. Since 2025, CSR has partnered with Portsmouth Hospitals University NHS Trust (PHU) to undertake a fully compliant clinical investigation of the Sentire® Surgical System, steadily accumulating real-world clinical data to support evidence-based research, training protocol development, and clinical adoption. To date, the Sentire® Surgical System has completed numerous complex procedures in the UK, spanning core specialties including urology, gynecology, and upper and lower gastrointestinal surgery. The investigation achieved the patient outcomes and the clinicians were very satisfied with the system's performance.

Deepening Global Presence with Localised Services

From its inception, CSR has embraced a "think global, act local" approach pursuing a global strategy empowered by local physicians and patients. In Europe, CSR formally established its UK subsidiary in 2025, initiating a one-stop service provision encompassing professional training, clinical

technical support, and after-sales service. The Company has already conducted multiple training sessions in the UK, helping clinical teams rapidly build proficiency and confidence in operating the Sentire® Surgical System, thereby establishing a solid foundation for scaled commercial rollout.

Full-Stack In-House R&D and Vertical Integration: The Foundation for High-Quality Global Expansion

CSR's full-stack in-house R&D capabilities and vertically integrated model are the foundation of its competitive advantage and global growth strategy. The Company's high level of technological integration not only drives strong clinical performance, supply chain resilience, and operational stability, but also enhances agility and supports long-term innovation.

Professor Samuel Au, Founder and CEO of Cornerstone Robotics, commented: "Receiving CE Certification marks a major milestone in Cornerstone Robotics' evolution from a technology innovator to a global clinical solutions provider. From our first clinical investigation in Portsmouth, UK, to achieving European regulatory approval, each step of the journey reflects our commitment to proprietary innovation, product excellence, and clinical value. Looking ahead, we will continue expanding into key global markets and partnering with leading medical institutions to bring high-quality surgical robotic solutions to more physicians and patients worldwide."

The CE Certification marks a major milestone in Cornerstone Robotics' expansion into the European market and broader global commercialization journey. In November 2025, the Company successfully completed an oversubscribed financing round of approximately US\$200 million, underscoring strong confidence from leading international investors in its long-term growth potential and global commercial capabilities. Supported by proprietary technological innovation and strong strategic resources, Cornerstone Robotics is well positioned to accelerate the global adoption of high-quality, accessible surgical robotic solutions for physicians and patients worldwide.

About Cornerstone Robotics (CSR)

Cornerstone Robotics (CSR) is an innovative surgical robotics unicorn driven by the vision of leading medical innovations for a healthier world. It advances surgical care with cutting-edge robotic systems that make high-quality healthcare more accessible and efficient globally. With three global R&D hubs and six business centers worldwide, the company has established a 30,000-square-meter manufacturing facility in China. Developed entirely in-house, the Sentire® Surgical System has completed multi-specialty clinical trials and received market approval across China, the European Union and Singapore, advancing high-quality surgical care worldwide.

To find out more information, please visit our website at <https://en.csrbtx.com/>

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