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Korea's SKIA receives US FDA 510(k) clearance for augmented reality surgical guidance system

June 1, 2026 | News

SKIA and Structure are positioned to offer a more accessible, cost-effective alternative to traditional surgical navigation

South Korea-based medtech innovator SKIA has announced that the US Food and Drug Administration (FDA) has granted 510(k) clearance for its augmented reality (AR) surgical guidance system, SKIA HEAD. This regulatory milestone clears the path for the system's commercial debut in the United States, supported by a strategic hardware partnership.

Unlike traditional navigation systems that require bulky, stationary equipment, SKIA HEAD is a tablet-based platform. The system converts preoperative medical imaging data into high-fidelity 3D anatomical reconstructions. These models are then projected directly onto the patient's body in real time, allowing surgeons to see beyond the surface and into the patient's internal anatomy.

A critical component of this portability and accuracy is the hardware integration: SKIA HEAD is powered by high-precision Structure Sensors. These medical-grade scanning sensors allow the system to map the patient's physical environment and anatomy with extreme accuracy, ensuring the AR overlay remains perfectly aligned during the procedure.

SKIA has confirmed it is planning to enter the US market through a formal partnership with Structure. By leveraging Structure's established sensor ecosystem and SKIA's software expertise, the two companies aim to make intuitive, high-precision AR guidance a standard in American operating rooms.

In India, the company's SKIA Body solution has successfully assisted in over 80 hernia surgeries. SKIA is currently developing AR platforms for breast cancer surgery, gastrointestinal operations, and even forensic applications.