Waldemar LINK Receives FDA 510(k) Clearance for Innovative Shoulder Arthroplasty Tool for Computer-Assisted Glenoid K-wire Placement

New technology offers a fast and efficient alternative to PSI and classical navigation systems for total shoulder replacement

LINK, a leader in innovative orthopedic solutions, is pleased to announce that on February 20, 2025, it received U.S. Food and Drug Administration (FDA) 510(k) clearance for the CORE Shoulder System. This novel shoulder arthroplasty tool is designed to assist in the placement of the K-wire for the glenoid component during total shoulder replacement procedures.

This next-generation device streamlines glenoid preparation by enabling surgeons to implant the K-wire precisely to the pre-operative plan with ease and confidence. The system can be used as soon as the CT scan is planned, enabling a lean, efficient operating room.

The compact CORE Shoulder system fits into a single portable case, and all of its sterile-field reusable components are provided in a single half-sized instrument tray. CORE operates without the need for installing bone markers, cameras, or permanent OR systems. The system tracks the live position of the handheld instrument relative to an untracked virtual anatomical model and provides targeting instructions wirelessly via a touch screen tablet.

“This clearance marks a pivotal step in our mission to simplify complex procedures while preserving accuracy,” Peter Willenborg, CEO of LINK Group states.

“With CORE, we’re putting powerful digital targeting tools directly into the hands of surgeons—no cords, no trackers, no waiting for guides. It’s part of our commitment to making advanced technology more accessible.”

The tool is compatible with the LINK Embrace Shoulder systems (Reverse and Anatomic TSA), integrating seamlessly into the standard surgical workflow.
LINK completed its first cases with CORE in June 2025, with broader availability anticipated later in the year.

For more information about the Embrace and CORE Shoulder, visit LINK at www.Link-Ortho.com.

About Digital Surgery at LinkBio
The Digital Surgery team was founded in the USA in 2019 as part of the LINK Group and strives to bring intuitive technology to all types of orthopedic operating rooms. With a focus on simplifying surgical procedures and improving patient outcomes, Digital Surgery will continue to deliver solutions that redefine the standard of care in joint reconstruction.

About LINK Group

Founded 1948 in Hamburg, Germany, LINK Group produced the first ever joint replacement prosthesis in Germany in 1963. With implantations in over 60 countries, it is among the leading players in the large joint replacement market. A pioneer of modern joint reconstruction, LINK has products which have set new standards from basic to extremely complex clinical situations giving it a respected name among the orthopedic community globally. The company is focused on further strengthening its leading position in revision surgery and expanding its portfolio of primary implants and enabling technology. Privately held, Helmut D. Link leads the company today with a long-term view on sustainable business development with absolutely no compromise on product and service quality, always following his saying that “We develop, produce and market only implants that we would be willing to have implanted in ourselves.” LINK Group is the parent company of LinkBio Corp.