



Orthopedic Driven Imaging
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For immediate release

Orthopedic Driven Imaging's achievement underscores the company's commitment to innovation and patient care. The newly cleared S-ODI See-arm™ represents a significant advancement in surgical imaging, offering clinicians improved clarity and accuracy during complex orthopedic procedures. This breakthrough technology is expected to support safer surgeries and enhanced patient outcomes.

Orthopedic Driven Imaging announces FDA 510(k) clearance for the S-ODI See-arm™

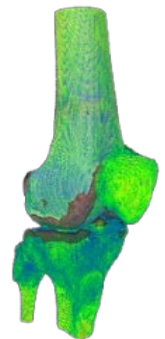
Gainesville, FL – 9/19/2025 – Orthopedic Driven Imaging (ODI), a medical technology company building the next generation of orthopedic imaging solutions, announced today that its surgical c-arm system (S-ODI See-arm™), developed in partnership with Imaging Engineering has achieved 510(k) clearance (K251650) from the U.S. Food and Drug Administration (FDA).

The approval marks the beginning of ODI's initiative to streamline surgical procedures and enhance clinical outcomes by leveraging an integrated ecosystem comprising advanced imaging hardware and AI-powered software, facilitating individualized and adaptable surgical planning and execution.

"Obtaining FDA 510(k) clearance for the S-ODI platform marks a defining moment for ODI and, we believe, for the future of orthopedic imaging," said Don Running, ODI's Chief Executive Officer. "This milestone marks the start of ODI's development of a fully integrated imaging platform for orthopedic surgery,"

By combining novel low-dose fluoroscopic hardware with an AI-enabled imaging solution, ODI addresses critical limitations of traditional 2D x-ray and high-cost CT systems. The company's ecosystem includes tools for 3D surgical planning, intraoperative guidance, and postoperative evaluation, all tailored to the unique anatomy and motion of each patient.

ODI's innovations are built on decades of scientific research, including dynamic kinematic analysis pioneered by Scott Banks, PhD, co-founder of ODI and Knee Society member. "With ODI, we are re-engineering advanced imaging and analysis, giving surgeons practical tools they can use with their patients across the entire continuum of care," said Dr. Banks. The company's





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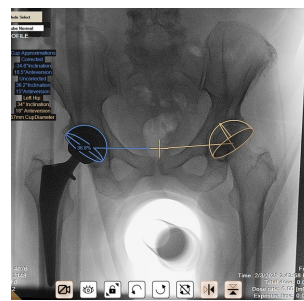
platform will close the information loop for surgeons, providing quantitative, real-time, dynamic 3D insights (4D) before, during, and after orthopedic procedures.

ODI's initial product portfolio of fluoroscopic systems includes a surgical ODI unit (S-ODI), a clinical unit for extremities (C-ODI x), a clinical unit for single joint imaging and arthrograms (C-ODI Lite), and a suite of associated AI-powered surgical apps. The initial value of ODI's technology will be evident in procedures such as total hip replacement, where enhanced imaging of the pelvis improves rotational accuracy and implant positioning.



About Orthopedic Driven Imaging (ODI)

Founded in 2023, ODI is pioneering a new era in orthopedic surgery by delivering a complete ecosystem for patient-specific visualization and planning. By unifying advanced fluoroscopic hardware with real-time software and AI, ODI empowers surgeons to make data-driven decisions, reduce operating time, and improve outcomes. Learn more at www.orthodriven.com.



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