

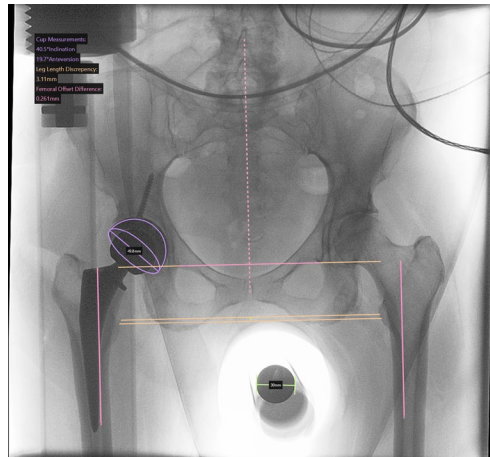
**FOR IMMEDIATE RELEASE**

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## Orthopedic Driven Imaging Announces FDA 510(k) Clearance for HipGuide™ — Its First FDA-Cleared Surgical Imaging App

*Intraoperative hip guidance software completes ODI's hardware-software ecosystem for total hip replacement*

**Orthopedic Driven Imaging (ODI)**, a medical technology company building the next generation of orthopedic imaging solutions, today announced that HipGuide™, its intraoperative surgical imaging software application, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). HipGuide is ODI's first FDA-cleared software application, and pairs directly with the company's S-ODI See-arm™ surgical C-arm platform to deliver real-time intraoperative imaging measurements during total hip replacement procedures.



HipGuide gives surgeons immediate, quantitative feedback on cup orientation and leg length and femoral offset during surgery. By making critical spatial data visible and actionable at the point of care, HipGuide helps address inaccurate component positioning which is one of the most consequential sources of variability in hip arthroplasty which remains a leading cause of dislocation, revision surgery, and patient dissatisfaction.

*“HipGuide clearance marks a pivotal milestone, not just for ODI, but for the surgeons and patients who stand to benefit most,” said Scott “Mac” McCaig, General Manager of ODI. “We set out to build an integrated imaging ecosystem where hardware and software work together seamlessly. HipGuide is the first proof point of that vision, and it opens the door to everything that comes next.”*

HipGuide is the first in a growing suite of surgical imaging applications that ODI is developing for orthopedic surgery. Coming additions to the pipeline include HipGuide 2.5D and HipPlan 2.5D, advanced applications that leverage machine learning to automate anatomical landmark identification and extend real-time imaging capabilities to pre-operative planning. Together, these applications are designed to bring quantitative, patient-specific insights to the full surgical continuum: before the patient enters the OR, throughout the procedure, and into postoperative evaluation.

HipGuide operates on ODI's S-ODI See-arm™ platform, which received FDA 510(k) clearance (K251650) in September 2025. The S-ODI See-arm™ was designed from the ground up to support software-driven orthopedic workflows, featuring a low-dose fluoroscopic architecture built for precise intraoperative image analysis. The combination of cleared hardware and cleared software now gives ODI a complete, commercially deployable solution for the high-volume total hip replacement market.



*“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 Scott Banks, PhD, co-founder of ODI and Knee Society member. “HipGuide represents the first step in closing the information loop for surgeons.”*

The clearance arrives ahead of ODI's participation in the Anterior Hip Foundation Annual Meeting this June, where the company will present in the Shark Tank session and feature the S-ODI See-arm™ in two live cadaver lab stations. The event represents a key commercial milestone as ODI accelerates its engagement with anterior hip surgeons, its primary initial target market, and begins building clinical familiarity with its fully integrated imaging platform.

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### 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, ODI empowers surgeons to make data-driven decisions, reduce operating time, and improve outcomes. ODI's product portfolio includes the S-ODI See-arm™ surgical C-arm, clinical imaging units for extremities and single-joint applications, and a growing suite of surgical guidance apps. Learn more at [www.orthodrive.com](http://www.orthodrive.com).

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