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Formus Labs, Pioneering Developer of AI-Powered 3D Orthopedic Surgery Planning Technology, Receives FDA Clearance

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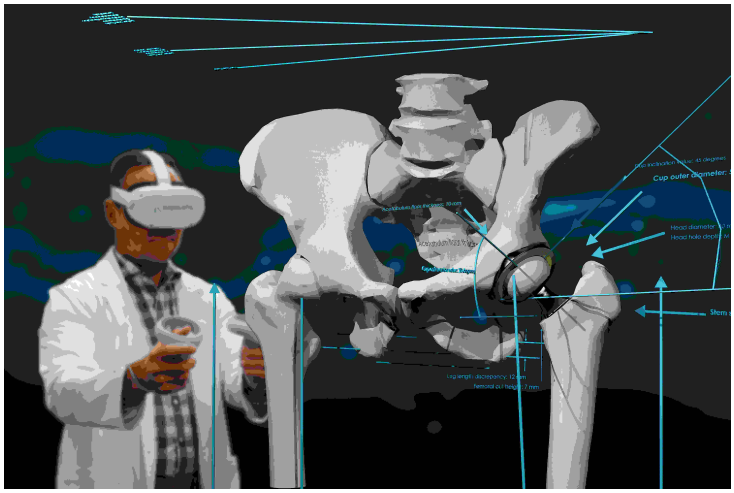
Formus combines AI and biomechanics to empower orthopedic surgeons with fully interactive 3D surgical plans that optimize the preoperative (pre-op) planning process



Formus Labs today announced it has received 510(k) clearance from the United States Food and Drug Administration (FDA) for Formus Hip as the first “automated radiological image processing software” for hip replacement pre-op planning. The New Zealand-founded company previously announced its intent to expand to the US and today’s announcement signifies Formus has cleared the last major hurdle before it can start making its solution widely available to surgeons and healthcare providers.

Nearly two million joints are replaced every year worldwide and that number is set to double by the end of the decade. Pre-op planning allows surgeons to create a custom surgical plan in advance. However, surgeons are often time constrained due to large caseloads and busy practices. This leaves little time for proactive preoperatively planning, consistently for every case. Additionally, planning individual surgeries can be very time-consuming, sometimes taking days or weeks to complete, which is simply not sustainable or scalable for surgeons with multiple procedures a day.

Formus expedites the joint replacement planning process by combining AI and computational biomechanics to calculate a patient’s implant fit and deliver digestible, actionable and fully-interactive 3D surgical plans. This innovative pre-operative planning technology provides a surgeon with a personalized curated patient surgical plan before the patient enters the operating room. This technology provides highly accurate outputs from scan to plan in under an hour.

“Today is a huge milestone in our journey to bring cutting-edge, pre-op surgery planning tools to surgeons, not only to make their work easier and more efficient, but also has the potential to improve the outcomes for their patients,” said Dr.

Ju Zhang, founder and CEO of Formus Labs. “FDA clearance serves as significant validation of the accuracy and rigor of our AI models. The surgeons who have used the Formus platform in Australia and New Zealand tell us they like having pre-op plans that make facing any unforeseen challenges on the day of the surgery easier to overcome because of the thorough understanding of each patient's physiology. It also has huge potential to save costs, time spent on logistics, and inventory. We’re excited to bring those same potential savings to providers in the US now too.”

“The technology underlying the Formus solution helps drive potential improvement in orthopedic patient outcomes. We’re thrilled the 510(k) approval now allows us to fully unlock our US commercialization strategy to achieve positive outcomes for more patients,” Vignesh Kumar, co-managing partner at GD1 and Formus board member.” Formus is a great example of a digital health solution that balances the delicate ‘iron triangle’ of cost, access, and quality while addressing those core pain points in an elegant manner.”