FOR IMMEDIATE RELEASE

ArthroTAK Receives FDA 510(k) Clearance for Expanded Indications, Extending Sutureless Fixation Platform Across the Body

ORLANDO, Fla. — September 4, 2026 — ArthroTAK, LLC, a medical device company developing sutureless soft tissue-to-bone fixation technology, today announced it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for expanded indications, extending the ArthroTAK® platform beyond its original shoulder applications into new areas of the body, including the knee, with additional anatomical applications in development.

“ArthroTAK is a new way to think about soft tissue-to-bone repair anywhere in the body. It eliminates the suture-tendon interface, the most common site of failure. It was designed to meet the needs of modern orthopedics, built for the ASC, sutureless, percutaneous, quick, easy, and cost-effective, all while exceeding the biomechanical strength of conventional repair techniques. We are excited to introduce instrumentation and techniques for several important sports medicine procedures in the immediate future,” said Dr. Amit Nathani, founder and designing surgeon of ArthroTAK, LLC.

The clearance marks a major milestone for the company, whose ArthroTAK® Tendon Anchor Kit already carries FDA clearance for biceps tenodesis procedures. This expanded clearance opens the door for ArthroTAK's “Drive. Deploy. Done.” fixation technology, a PEEK implant designed for deployment in approximately 45 to 60 seconds without the need for suture management, to reach new anatomical applications. The company's first area of focus under this expanded clearance is the knee, where it will bring its technology to surgeons performing Lateral Extra-articular Tenodesis (LET), a procedure increasingly used alongside ACL reconstruction to improve rotational stability and reduce re-tear rates.

This next chapter builds on early momentum from ArthroTAK's limited release for biceps tenodesis, during which the company has completed more than 80 surgical cases. That early experience has brought strong surgeon feedback and growing case volume, giving the company confidence as it extends its sutureless fixation platform into new procedures and anatomical areas.

Building a Platform Across the Body

While LET represents ArthroTAK's near-term commercial priority in the knee, the company is continuing to invest in instrumentation and design work intended to extend its sutureless fixation platform to additional anatomical applications throughout the body, including the shoulder, foot and ankle, wrist, and other joints where soft tissue-to-bone fixation is required. ArthroTAK intends to pursue additional regulatory clearances as this instrumentation matures, and will identify specific indications and timelines as they are confirmed.

“What excites us most about this clearance isn't just the knee opportunity in front of us; it's the platform it validates,” said Justin J. Kaler, General Manager of ArthroTAK LLC. “We designed ArthroTAK to be anatomy-agnostic at its core. Knee is our next chapter, but it's one chapter in a much bigger story about how sutureless fixation can change soft tissue attachment across orthopedic surgery.”

About ArthroTAK, LLC

ArthroTAK, LLC is an Orlando-based medical device company developing innovative, sutureless soft-tissue fixation technology for sports medicine and orthopedic surgery. The company’s flagship product, the ArthroTAK™ Tendon Anchor Kit, is a single-use, single-step PEEK implant system designed to simplify bone-to-tendon fixation, reduce surgical time, and lower procedural costs. To learn more, visit www.arthrotak.com.