Gmreis Receives FDA 510(k) Clearance for MENISCUS VERSAFLEX™ – Expanding Its Sports Medicine Portfolio

February 25, 2026 - Gmreis has received U.S. FDA 510(k) clearance (K254188) for its MENISCUS VERSAFLEX™ all-inside meniscal repair system, marking a significant milestone in the company's continued expansion into the global sports medicine market.

The MENISCUS VERSAFLEX™ system consists of PEEK buttons combined with a #2-0 knotless suture configuration, designed to enable an "all-inside" treatment approach for meniscal injuries. The device features a flexible needle that allows surgeons to access all zones of the meniscus through the standard anterior portal, while its ergonomic application mechanism enables one-handed deployment.

This clearance strengthens Gmreis' position in arthroscopic soft tissue repair and strategically completes its sports medicine portfolio by adding a modern, minimally invasive meniscal repair solution. The addition of MENISCUS VERSAFLEX™ complements the company's existing orthopedic and trauma offerings, reinforcing its commitment to providing comprehensive solutions across key subspecialties.

With FDA clearance secured, Gmreis continues to advance its international growth strategy, expanding its presence across international markets while enhancing its product ecosystem in sports medicine.