GMReis Strengthens Vertical Integration with FDA-Cleared In-House Braided Surgical Sutures

August 25, 2026 / GMReis has received FDA 510(k) clearance K253910 for its STITCH Surgical Sutures, marking an important milestone in the company's strategy to vertically integrate critical manufacturing technologies for sports medicine and soft-tissue fixation.

A key differentiator behind the clearance is GMReis' in-house braiding capability. The company controls the development and manufacturing of its high-strength braided sutures within its own production facility, a specialized capability held by a relatively limited number of orthopedic device manufacturers.

The STITCH portfolio includes non-absorbable, high-strength surgical sutures ranging from USP 4-0 through USP 5, as well as braided sleeves engineered for integration with suture anchors and flexible fixation systems.

GMReis' braiding facility and manufacturing process were validated to produce these braided components within a controlled cleanroom environment without requiring a conventional post-braiding washing process. Eliminating this manufacturing step reduces the use of chemical mixtures, detergents and other processing agents typically associated with conventional washing processes while simplifying the manufacturing flow.

By bringing braiding technology in-house, GMReis gains direct control over critical product characteristics including fiber selection, diameter, braid architecture, mechanical performance and product configuration. This capability also provides greater flexibility to develop proprietary braided structures specifically engineered for different orthopedic applications.

The FDA clearance therefore represents more than the addition of another product family to GMReis' U.S. portfolio. It validates an important internal manufacturing technology platform that can support the development of sutures and braided sleeves for the company's next generation of suture anchors, flexible fixation systems and soft-tissue repair technologies.

"Vertical integration of braiding technology gives GMReis greater control over product development, manufacturing and innovation," the company said. "We can engineer the braided component together with the implant rather than treating the suture as a separate component, creating new opportunities for integrated orthopedic fixation solutions."
The clearance further strengthens GMReis' technology platform for sports medicine, foot and ankle, hand and wrist, trauma and soft-tissue fixation, while supporting the company's continued expansion in the U.S. orthopedic market.

GMReis
+55 19 997447603
www.gmreis.com.br
export2@gmreis.com.br