FDA 510(k) Clearance Expands GMReis Versalock Upper Limb Portfolio in the U.S.

May 19, 2026 / GMReis announces the FDA 510(k) clearance of its new 3.5 mm Versalock Diaphyseal Locking Plates for the radius and ulna, further strengthening the company's growing upper limb fixation portfolio in the United States market.

The newly cleared system includes anatomical plates designed for the fixation of fractures, osteotomies, and pseudoarthrosis of the radius and ulna, featuring variable-angle locking technology and titanium construction. The addition complements the existing Versalock family, reinforcing GMReis' strategy of offering comprehensive upper extremity solutions — from scapula to fingers.

With this milestone, GMReis continues to expand its presence in the U.S. orthopedic market through strategic private label partnerships, providing OEM and distribution partners with innovative, high-quality fixation systems supported by international regulatory approvals.

The company's long-term objective is to become a leading upper limb private label manufacturing partner in the Americas, combining manufacturing flexibility, broad portfolio capabilities, and competitive product development.

The FDA clearance represents another important step in GMReis' international growth strategy and commitment to delivering advanced orthopedic solutions worldwide.

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