FDA 510(k) Premarket Notification

K253867 FiberLocker Implant

CLEARED

Jan 2, 2026
30 days to decision

K253867 · Product code: **OWX** · Orthopedic
Source: https://www.510kdatabase.net/k253867/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Non-absorbable, Orthopaedics, Reinforcement Of Tendon (OWX)
Date received	Dec 3, 2025
Decision date	Jan 2, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FiberLocker Instrument ; FiberLocker PowerUnit

APPLICANT

Company	**ZuriMED Technologies AG**
Location	Zurich, CH
Contact	Elias Bachmann
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Kelliann Payne

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov