

K241219 FiberLocker System: FiberLocker Implant (SpeedPatch PET), FiberLocker Instrument (FiberLocker Instrument SN)Dec 11, 2024
224 days to decisionK241219 · Product code: **OWX** · Orthopedic
Source: <https://www.510kdatabase.net/k241219/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Non-absorbable, Orthopaedics, Reinforcement Of Tendon (OWX)
Date received	May 1, 2024
Decision date	Dec 11, 2024
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241219/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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