FDA 510(k) Premarket Notification

CLEARED

K252022 OSSIOfiber® Interference Screw

Aug 19, 2025
50 days to decision

K252022 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k252022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Jun 30, 2025
Decision date	Aug 19, 2025
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**OSSIO , Ltd.**
Location	Caesarea, IL
Contact	Taly Lindner
Website	https://ossio.com
510(k) history	20 submissions · 20 cleared · 2019-2026

OSSIO, Ltd. specializes in orthopedic fixation and soft tissue repair devices. The company operates with a manufacturing facility in Caesarea, IL. OSSIO has received FDA 510(k) clearances from total submissions since 2019. The company's portfolio focuses entirely on orthopedic solutions, including fixation nails, suture anchors, interference screws, and compression staples. The latest clearance in 2026 reflects continued regulatory activity and product development. OSSIO's OSSIOfiber® product family represents the company's core technology platform for orthopedic fixation...

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Dave McGurl

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252022/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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