

K213596 OSSIOfiber Compression Screw, 3.5mmDec 21, 2021
39 days to decisionK213596 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k213596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 12, 2021
Decision date	Dec 21, 2021
Days to decision	39 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	David McGurl

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

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Device record: <https://www.510kdatabase.net/k213596/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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