

**K221193 OSSIOfiber Compression Screw, OSSIOfiber Compression Screw, 6.5mm**Dec 23, 2022  
242 days to decisionK221193 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k221193/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Apr 25, 2022
Decision date	Dec 23, 2022
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OSSIO , Ltd.</b>
Location	Caesarea, IL
Contact	Taly Lindner
Website	<a href="https://ossio.com">https://ossio.com</a>
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**

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Consulting firm	<b>Mcra, LLC</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k221193/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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