

**K201803 OSSIOfiber™ Hammertoe Fixation System/OSSIOfiber™ Hammertoe Fixation Implant**Oct 16, 2020  
108 days to decisionK201803 · Product code: HTY · Orthopedic  
Source: <https://www.510kdatabase.net/k201803/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Jun 30, 2020
Decision date	Oct 16, 2020
Days to decision	108 days
Third-party review	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...