

K230750 OSSIOfiber® Cannulated Trimmable Fixation NailSep 13, 2023
180 days to decisionK230750 · Product code: HTY · Orthopedic
Source: <https://www.510kdatabase.net/k230750/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Mar 17, 2023
Decision date	Sep 13, 2023
Days to decision	180 days
Third-party review	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...
