FDA 510(k) Premarket Notification

CLEARED

K203465 OSSIOfiber Cannulated Trimmable Fixation Nail, OSSIOfiber Trimmable Fixation Nail, OSSIOfiber Trimmable Fixation Nail, Cannulated Design

Jan 6, 2021
43 days to decision

K203465 · Product code: **HTY** · Orthopedic
Source: https://www.510kdatabase.net/k203465/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Nov 24, 2020
Decision date	Jan 6, 2021
Days to decision	43 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