FDA 510(k) Premarket Notification

K212594 OSSIOfiber® Staple

CLEARED

Jan 21, 2022
158 days to decision

K212594 · Product code: **MNU** · Orthopedic
Source: https://www.510kdatabase.net/k212594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Absorbable (MNU)
Date received	Aug 16, 2021
Decision date	Jan 21, 2022
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**OSSIO , Ltd.**
Location	Caesarea, IL
Contact	Taly Linder
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