CLEARED

K190652 OSSIOfiber™ Hammertoe Fixation System/OSSIOfiber™ Hammertoe Fixation Implant

Mar 6, 2020
359 days to decision

K190652 · Product code: **HTY** · Orthopedic
Source: https://www.510kdatabase.net/k190652/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Mar 13, 2019
Decision date	Mar 6, 2020
Days to decision	359 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...