FDA 510(k) Premarket Notification

K242650 zLOCK Lumbar Facet Fixation System

CLEARED

Sep 20, 2024
16 days to decision

K242650 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k242650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Sep 4, 2024
Decision date	Sep 20, 2024
Days to decision	16 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zygofix , Ltd.**
Location	Misgav, IL
Contact	Levy Ofer
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Justin Eggleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov