FDA 510(k) Premarket Notification

K240085 zLOCK Lumbar Facet Fixation System

CLEARED

Apr 18, 2024
98 days to decision

K240085 · Product code: **MRW** · Orthopedic
Source: https://www.510kdatabase.net/k240085/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Facet Screw Spinal Device (MRW)
Date received	Jan 11, 2024
Decision date	Apr 18, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zygofix , Ltd.**
Location	Misgav, IL
Contact	Ofer Levy
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

CLINICAL EVIDENCE - NCT04229316

Safety And Efficacy Assessment of the zLock Facet Fusion System- A Pilot Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	24 patients (actual)
Study sites	1 site
Condition studied	Low Back Pain
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	May 31, 2024
Sponsor	ZygoFix (Industry)

Primary outcome

Safety assessment - no device related reoperation

Secondary outcome

Efficacy assessment - achieving facet fusion 12 months post procedure

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04229316