FDA 510(k) Premarket Notification

CLEARED

K243973 FIX-L PEEK PLIF and T-PLIF System

Jun 12, 2025
171 days to decision

K243973 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k243973/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 23, 2024
Decision date	Jun 12, 2025
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jeil Medical Corporation**
Location	Deer Field, IL, US
Contact	Dajung Lee
510(k) history	53 submissions · 53 cleared · 2002-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k243973/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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