FDA 510(k) Premarket Notification

K251003 X-PAC® LLIF Expandable Lateral Cage System

CLEARED

Jun 25, 2025
85 days to decision

K251003 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k251003/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 1, 2025
Decision date	Jun 25, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Expanding Innovations, Inc.**
Location	Mountain View, CA, US
Contact	Robert Jaramillo
510(k) history	8 submissions · 8 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Helix Medical, LLC**
Contact	Carolyn Guthrie

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