FDA 510(k) Premarket Notification

K243668 ProLift Pivot Expandable Spacer System

CLEARED

Jan 23, 2025
57 days to decision

K243668 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k243668/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 27, 2024
Decision date	Jan 23, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Life Spine, Inc.**
Location	Hoffman Estates, IL, US
Contact	Angela Batker
510(k) history	82 submissions · 82 cleared · 2011-2026