FDA 510(k) Premarket Notification

K261430 TruLift Expandable System

CLEARED

Jul 28, 2026
89 days to decision

K261430 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k261430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Apr 30, 2026
Decision date	Jul 28, 2026
Days to decision	89 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
Website	http://www.lifespine.com/
510(k) history	85 submissions · 85 cleared · 2011-2026

Life Spine, Inc. is a spinal medical device company headquartered in Huntley, Illinois. Founded in 2004, the company develops innovative solutions for spinal pathology across the cervical, thoracic, and lumbar spine. Life Spine serves 32 countries and employs over 70 people worldwide. The company has received FDA 510(k) clearances from total submissions since 2011. Life Spine specializes exclusively in Orthopedic devices, with a focus on minimally invasive spinal fusion solutions. The latest clearance was in 2026, confirming active regulatory engagement. Life Spine's prod...