FDA 510(k) Premarket Notification

K203361 ProLift Wedge Expandable Spacer System

CLEARED

Mar 17, 2021
121 days to decision

K203361 · Product code: **MAX** · Orthopedic
Source: https://www.510kdatabase.net/k203361/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 16, 2020
Decision date	Mar 17, 2021
Days to decision	121 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