

K180642 Pro-Link® Ti Stand-Alone Cervical Spacer SystemMay 10, 2018
59 days to decisionK180642 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k180642/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Mar 12, 2018
Decision date	May 10, 2018
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Life Spine, Inc.
Location	Hoffman Estates, IL, US
Contact	Randy Lewis
Website	http://www.lifespine.com/
510(k) history	82 submissions · 82 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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180642/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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