FDA 510(k) Premarket Notification

K183430 Modular Spinal Fixation System

CLEARED

Mar 13, 2019
92 days to decision

K183430 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k183430/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Dec 11, 2018
Decision date	Mar 13, 2019
Days to decision	92 days
Third-party review	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	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.net
Device record: https://www.510kdatabase.net/k183430/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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