FDA 510(k) Premarket Notification

K162266 The Cranial Fusion System

CLEARED

May 1, 2017
263 days to decision

K162266 · Product code: **NKG** · Orthopedic
Source: https://www.510kdatabase.net/k162266/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Posterior Cervical Screw System (NKG)
Date received	Aug 11, 2016
Decision date	May 1, 2017
Days to decision	263 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...