FDA 510(k) Premarket Notification

K242827 A8 INTEGR8™ Porous Pedicle Screws

CLEARED

Oct 20, 2025
397 days to decision

K242827 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k242827/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Sep 18, 2024
Decision date	Oct 20, 2025
Days to decision	397 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Allumin8, Inc.**
Location	Springfield, MO, US
Contact	Alyssa Huffman
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**DuVal & Associates, P.A.**
Contact	Jessica Czamanski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov