

**K242827 A8 INTEGR8™ Porous Pedicle Screws**Oct 20, 2025  
397 days to decisionK242827 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k242827/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>DuVal &amp; Associates, P.A.</b>
Contact	Jessica Czamanski

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242827/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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