

K252437 JAZZ Spinal SystemAug 28, 2025
27 days to decisionK252437 · Product code: **NKB** · Orthopedic
Source: <https://www.510kdatabase.net/k252437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Aug 1, 2025
Decision date	Aug 28, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Implanet
Location	Allee Francois Magendie, FR
Contact	Regis Le Couedic
510(k) history	3 submissions · 3 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Christine Scifert

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

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