

**K240392 JAZZ Spinal System**May 6, 2024  
88 days to decisionK240392 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k240392/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received         | Feb 8, 2024                                   |
| Decision date         | May 6, 2024                                   |
| Days to decision      | 88 days                                       |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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

**REGULATORY CONSULTANT**

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|-----------------|-------------------|
| Consulting firm | <b>MRC Global</b> |
| 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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