

**K231844 ProMIS™ Fixation System**Jul 7, 2023  
15 days to decisionK231844 · Product code: **NKB** · Orthopedic  
Source: <https://www.510kdatabase.net/k231844/>**SUBMISSION DETAILS**

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|                       |                                               |
|-----------------------|-----------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Special                                       |
| Device classification | Thoracolumbosacral Pedicle Screw System (NKB) |
| Date received         | Jun 22, 2023                                  |
| Decision date         | Jul 7, 2023                                   |
| Days to decision      | 15 days                                       |
| Third-party review    | No                                            |
| Combination product   | No                                            |
| PCCP authorized       | No                                            |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Premia Spine, Ltd.</b>             |
| Location       | Ramat Poleg, IL                       |
| Contact        | Dorit Winitz                          |
| 510(k) history | 6 submissions · 6 cleared · 2015-2023 |

**REGULATORY CONSULTANT**

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|-----------------|-----------------------------|
| Consulting firm | <b>Hogan Lovells US LLP</b> |
| Contact         | Janice M. Hogan             |

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/k231844/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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