

**K052404 DENALI DEFORMITY SYSTEM**May 23, 2006  
264 days to decisionK052404 · Product code: **KWP** · Orthopedic  
Source: <https://www.510kdatabase.net/k052404/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Appliance, Fixation, Spinal Interlaminar (KWP) |
| Date received         | Sep 1, 2005                                    |
| Decision date         | May 23, 2006                                   |
| Days to decision      | 264 days                                       |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>K2m, LLC</b>                       |
| Location       | Leesburg, VA, US                      |
| Contact        | RICHARD W WOODS                       |
| 510(k) history | 8 submissions · 8 cleared · 2005-2018 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052404/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026