

**K081501 SOLITAIRE ANTERIOR SPINAL SYSTEM**Jul 2, 2008  
34 days to decisionK081501 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k081501/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                  |
| Submission type       | Traditional   |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD) |
| Date received         | May 29, 2008  |
| Decision date         | Jul 2, 2008   |
| Days to decision      | 34 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biomet Spine</b>                     |
| Location       | Warsaw, IN, US                          |
| Contact        | VIVIAN KELLY                            |
| 510(k) history | 19 submissions · 18 cleared · 2007-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081501/> 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 May 17, 2026