

**K112068 SYNTHES ZERO-P VARIABLE ANGLE (VA)**

Nov 7, 2011  
 110 days to decision

K112068 · Product code: **OVE** · Orthopedic  
 Source: <https://www.510kdatabase.net/k112068/>

**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                    |
| Submission type       | Traditional   |
| Device classification | Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE) |
| Date received         | Jul 20, 2011  |
| Decision date         | Nov 7, 2011   |
| Days to decision      | 110 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Synthes Spine Co.Lp</b>              |
| Location       | West Chester, PA, US                    |
| Contact        | STACEY BONNELL                          |
| 510(k) history | 18 submissions · 18 cleared · 2005-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k112068/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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