

**K091278 VALEO SPACER SYSTEM**

Jan 28, 2010  
272 days to decision

K091278 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k091278/>

**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Intervertebral Fusion Device With Bone Graft, Lumbar (MAX) |
| Date received         | May 1, 2009  |
| Decision date         | Jan 28, 2010   |
| Days to decision      | 272 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Amedica Corp.</b>                    |
| Location       | Salt Lake City, UT, US                  |
| Contact        | ROBERT M WOLFARTH                       |
| 510(k) history | 16 submissions · 16 cleared · 2002-2018 |

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

Device record: <https://www.510kdatabase.net/k091278/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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