

**K111041 MINI VARIABLE SYSTEM**Jun 6, 2011  
53 days to decisionK111041 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k111041/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Plate, Fixation, Bone (HRS)        |
| Date received         | Apr 14, 2011                       |
| Decision date         | Jun 6, 2011                        |
| Days to decision      | 53 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Orthohelix Surgical Designs, Inc.</b> |
| Location       | Cleveland, OH, US                        |
| Contact        | DEREK LEWIS                              |
| 510(k) history | 25 submissions · 25 cleared · 2005-2014  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111041/> 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