

**K212996 Sterile PHALINX Hammertoe System**Nov 16, 2021  
57 days to decisionK212996 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k212996/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Screw, Fixation, Bone (HWC)        |
| Date received         | Sep 20, 2021                       |
| Decision date         | Nov 16, 2021                       |
| Days to decision      | 57 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Wrightmedicaltechnologyinc</b>         |
| Location       | Arlington, TN, US                         |
| Contact        | Michael Mullins                           |
| 510(k) history | 302 submissions · 291 cleared · 1993-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212996/> 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 13, 2026