

**K181399 FIREFLY® Pedicle Screw Navigation Guide**Jul 24, 2018  
56 days to decisionK181399 · Product code: **PQC** · Orthopedic  
Source: <https://www.510kdatabase.net/k181399/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Pedicle Screw Placement Guide (PQC) |
| Date received         | May 29, 2018                        |
| Decision date         | Jul 24, 2018                        |
| Days to decision      | 56 days                             |
| Third-party review    | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mighty Oak Medical, Inc.</b>       |
| Location       | Englewood, CO, US                     |
| Contact        | Mark A. Wylie                         |
| 510(k) history | 5 submissions · 5 cleared · 2015-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181399/> 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 26, 2026