

**K160069 Sonoma Fibula Repair System**Mar 10, 2016  
57 days to decisionK160069 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k160069/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received         | Jan 13, 2016  |
| Decision date         | Mar 10, 2016  |
| Days to decision      | 57 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|--|
| Company        | <b>Sonoma Orthopedics Products, Inc.</b> |
| Location       | Santa Rosa, CA, US                       |
| Contact        | Rick Epstein                             |
| 510(k) history | 2 submissions · 2 cleared · 2015-2016    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160069/> 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