

**K172157 DePuy Synthes Femoral Recon Nail System**Nov 14, 2017  
119 days to decisionK172157 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k172157/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received         | Jul 18, 2017  |
| Decision date         | Nov 14, 2017  |
| Days to decision      | 119 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Synthes USA Products, LLC</b>        |
| Location       | West Chester, PA, US                    |
| Contact        | Alexander Zwahlen                       |
| 510(k) history | 60 submissions · 60 cleared · 2010-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172157/> 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 16, 2026