

**K201315 PERFORM Humeral System – Stem**Sep 11, 2020  
116 days to decisionK201315 · Product code: **PAO** · Orthopedic  
Source: <https://www.510kdatabase.net/k201315/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Shoulder, Semi-constrained, Metal/polymer + Additive, Cemented (PAO) |
| Date received         | May 18, 2020   |
| Decision date         | Sep 11, 2020   |
| Days to decision      | 116 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Tornier, Inc.</b>                    |
| Location       | Beverly, MA, US                         |
| Contact        | Renee Stoffel                           |
| 510(k) history | 51 submissions · 51 cleared · 2000-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201315/> 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 14, 2026