

K151293 Aequalis Ascend Flex Shoulder System, Aequalis Reversed Shoulder ProsthesisSep 24, 2015
132 days to decisionK151293 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k151293/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS) |
| Date received | May 15, 2015 |
| Decision date | Sep 24, 2015 |
| Days to decision | 132 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Tornier S.A.S. |
| Location | Bloomington, MN, US |
| Contact | Severine Bonneton |
| 510(k) history | 20 submissions · 19 cleared · 2013-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151293/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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