

K241878 Tornier Humeral Reconstruction System (Tornier HRS)Dec 6, 2024
161 days to decisionK241878 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k241878/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS) |
| Date received | Jun 28, 2024 |
| Decision date | Dec 6, 2024 |
| Days to decision | 161 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Tornier Perform Humeral System - Stem (Tornier PHS-Stem) |

APPLICANT

| | |
|----------------|--|
| Company | Stryker Corporation (Tornier, Inc.) |
| Location | Bloomington, MN, US |
| Contact | Stefanie Tarara |
| 510(k) history | 2 submissions · 2 cleared · 2024-2024 |

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