

K251686 Tornier Humeral Reconstruction System Max (Tornier HRS Max)

Oct 30, 2025
150 days to decision

K251686 · Product code: **KWT** · Orthopedic
Source: <https://www.510kdatabase.net/k251686/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Non-constrained, Metal/polymer Cemented (KWT)
Date received	Jun 2, 2025
Decision date	Oct 30, 2025
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tornier, Inc.
Location	Beverly, MA, US
Contact	Stefanie Tarara
510(k) history	51 submissions · 51 cleared · 2000-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251686/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026