

K143374 BLUEPRINT Patient Specific InstrumentationApr 8, 2015
134 days to decisionK143374 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k143374/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Nov 25, 2014
Decision date	Apr 8, 2015
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143374/> 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