

K161789 BLUEPRINT Patient Specific InstrumentationDec 27, 2016
181 days to decisionK161789 · Product code: **KWS** · Orthopedic
Source: <https://www.510kdatabase.net/k161789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Shoulder, Semi-constrained, Metal/polymer Cemented (KWS)
Date received	Jun 29, 2016
Decision date	Dec 27, 2016
Days to decision	181 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

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