

**K203315 BLUEPRINT™ Patient Specific Instrumentation**Apr 15, 2021  
156 days to decisionK203315 · Product code: **KWS** · Orthopedic  
Source: <https://www.510kdatabase.net/k203315/>**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	Nov 10, 2020
Decision date	Apr 15, 2021
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tornier S.A.S.</b>
Location	Bloomington, MN, US
Contact	Aymen Azaiez
510(k) history	20 submissions · 19 cleared · 2013-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203315/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026