

K232265 BLUEPRINT™ Patient Specific InstrumentationFeb 21, 2024
205 days to decisionK232265 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k232265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jul 31, 2023
Decision date	Feb 21, 2024
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	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/k232265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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