

K220914 Tornier Perform Humeral System – FractureOct 14, 2022
198 days to decisionK220914 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k220914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Mar 30, 2022
Decision date	Oct 14, 2022
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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