

K220418 Tornier Perform Humeral System – StemlessSep 14, 2022
212 days to decisionK220418 · Product code: **PKC** · Orthopedic
Source: <https://www.510kdatabase.net/k220418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Total Anatomic Shoulder, Uncemented Metaphyseal Humeral Stem With No Diaphyseal Incursion, Semi-constrained (PKC)
Date received	Feb 14, 2022
Decision date	Sep 14, 2022
Days to decision	212 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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