

K230352 Tornier Humeral Nail and Tornier Long Humeral NailOct 31, 2023
264 days to decisionK230352 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k230352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 9, 2023
Decision date	Oct 31, 2023
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230352/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026