

K253991 Fitbone™ Trochanteric, FITBONE® Transport and Lengthening System, FITBONE® TAAMay 8, 2026
147 days to decisionK253991 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k253991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Dec 12, 2025
Decision date	May 8, 2026
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix Srl
Location	Rockville, MD, US
Contact	Elvira Taccarelli
510(k) history	38 submissions · 38 cleared · 1995-2026

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