

K250112 Fitbone™ TrochantericApr 10, 2025
84 days to decisionK250112 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k250112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jan 16, 2025
Decision date	Apr 10, 2025
Days to decision	84 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	36 submissions · 36 cleared · 1995-2025

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