

K250197 Estremo Fibular NailOct 17, 2025
267 days to decisionK250197 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k250197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jan 23, 2025
Decision date	Oct 17, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Citieffe S.R.L.
Location	Ormond Beach, FL, US
Contact	Federica Giovetti
510(k) history	8 submissions · 8 cleared · 2013-2025

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