

K232648 RODEO Telescopic NailMay 3, 2024
246 days to decisionK232648 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k232648/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Aug 31, 2023
Decision date	May 3, 2024
Days to decision	246 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

REGULATORY CONSULTANT

Consulting firm	Orthofix US, LLC
Contact	Mitchell Dhority

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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