

K250559 GMReis Fibula Nail SystemJun 12, 2025
107 days to decisionK250559 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k250559/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Feb 25, 2025
Decision date	Jun 12, 2025
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gm Dos Reis Industria E Comercio
Location	Campinas, BR
Contact	Guilherme Esteves Pontes
510(k) history	2 submissions · 2 cleared · 2025-2025

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