

K172699 Agile NailApr 23, 2018
228 days to decisionK172699 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k172699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Sep 7, 2017
Decision date	Apr 23, 2018
Days to decision	228 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Orthofix Srl
Location	Rockville, MD, US
Contact	Gianluca Ricadona
510(k) history	36 submissions · 36 cleared · 1995-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172699/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026