

K210157 SOLE Medial Column Fusion PlateApr 20, 2021
89 days to decisionK210157 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k210157/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 21, 2021
Decision date	Apr 20, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Wagoner Consulting, LLC
Contact	Cheryl Wagoner

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

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