

K211843 PolyLock Plating SystemMar 4, 2022
262 days to decisionK211843 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k211843/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 15, 2021
Decision date	Mar 4, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fusion Orthopedics
Location	Mesa, AZ, US
Contact	Eli Jacobson
510(k) history	2 submissions · 2 cleared · 2022-2024

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