

**K252949 Geminus Volar Distal Radius Plating System**Nov 13, 2025  
58 days to decisionK252949 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k252949/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 16, 2025
Decision date	Nov 13, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skeletal Dynamics, Inc.</b>
Location	Miami, FL, US
Contact	Daniel E. Gallego
510(k) history	20 submissions · 20 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252949/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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