

**K212297 Omni Foot and Ankle Plating System**Aug 20, 2021  
29 days to decisionK212297 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k212297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 22, 2021
Decision date	Aug 20, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Extremity Medical, LLC</b>
Location	Parsippany, NJ, US
Contact	Brian Smekal
510(k) history	28 submissions · 28 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212297/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026