

K221362 Omni Foot and Ankle Plating SystemJun 10, 2022
30 days to decisionK221362 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k221362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	May 11, 2022
Decision date	Jun 10, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Exremity Medical, LLC
Location	Parsippany, NJ, US
Contact	Mary Hoffman
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221362/> 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 27, 2026