

**K250498 BPS Wrist Fracture System**Mar 17, 2025  
25 days to decisionK250498 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k250498/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 20, 2025
Decision date	Mar 17, 2025
Days to decision	25 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthonovis, Inc.</b>
Location	Palm Coast, FL, US
Contact	Ken West
510(k) history	5 submissions · 5 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Simple Path, LLC</b>
Contact	Tawney Schwarz

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

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