

**K242343 BPS Wrist Fracture System**Oct 4, 2024  
58 days to decisionK242343 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k242343/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 7, 2024
Decision date	Oct 4, 2024
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>Orthonovis, Inc.</b>
Location	Palm Coast, FL, US
Contact	Kenneth West
510(k) history	5 submissions · 5 cleared · 2022-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Technologies</b>
Contact	Hannah Taggart

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242343/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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