

K250055 BPS - Bone Fragment Fixation Plates, Screws and WashersFeb 6, 2025
27 days to decisionK250055 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k250055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 10, 2025
Decision date	Feb 6, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Simple Path, LLC
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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250055/> 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 13, 2026