

**K212841 Pectus Blu Support Bar System**Jan 7, 2022  
122 days to decisionK212841 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k212841/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 7, 2021
Decision date	Jan 7, 2022
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet Micofixation</b>
Location	Jacksonville, FL, US
Contact	Mark Wladowski
510(k) history	3 submissions · 3 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>MRC Global, LLC</b>
Contact	Danielle Besal

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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