

**K213712 Pectus Support Bar System**Mar 11, 2022  
107 days to decisionK213712 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k213712/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Nov 24, 2021
Decision date	Mar 11, 2022
Days to decision	107 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomet Microfixation</b>
Location	Jacksonville, FL, US
Contact	Mark Wladkowski
510(k) history	24 submissions · 24 cleared · 2012-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>MRC Global</b>
Contact	Christine Scifert

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/k213712/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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