

**K212608 RibFix Blu Thoracic Fixation System**Apr 22, 2022  
248 days to decisionK212608 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k212608/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Plate, Fixation, Bone (HRS)        |
| Date received         | Aug 17, 2021                       |
| Decision date         | Apr 22, 2022                       |
| Days to decision      | 248 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        | Lauren Jasper                           |
| 510(k) history | 24 submissions · 24 cleared · 2012-2024 |

**REGULATORY CONSULTANT**

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|-----------------|------------------------|
| Consulting firm | <b>MRC Global, LLC</b> |
| Contact         | Christine Scifert      |

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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