

K261002 Pectus Blu SystemJun 2, 2026
68 days to decisionK261002 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k261002/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 26, 2026
Decision date	Jun 2, 2026
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomet Microfixation
Location	Jacksonville, FL, US
Contact	Jose Ponce
510(k) history	25 submissions · 25 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Danielle Besal

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

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