FDA 510(k) Premarket Notification

K261002 Pectus Blu System

CLEARED

Jun 2, 2026
68 days to decision

K261002 · 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