

**K251050 Pectus Versa System**Dec 19, 2025  
260 days to decisionK251050 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k251050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 3, 2025
Decision date	Dec 19, 2025
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gm Dos Reis Industria E Comercio</b>
Location	Campinas, BR
Contact	Guilherme Esteves Pontes
510(k) history	2 submissions · 2 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251050/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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