

**K260411 PC Fix System**Apr 24, 2026  
74 days to decisionK260411 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k260411/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Feb 9, 2026
Decision date	Apr 24, 2026
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Chest Wall Innovations, Inc.</b>
Location	Hershey, PA, US
Contact	Kenneth Kremer
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sagemar Medical, LLC</b>
Contact	Jennifer Palinchik

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/k260411/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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