

**K232324 StealthFix Intraosseous Fixation System**Aug 30, 2023  
27 days to decisionK232324 · Product code: **JDR** · Orthopedic  
Source: <https://www.510kdatabase.net/k232324/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Staple, Fixation, Bone (JDR)
Date received	Aug 3, 2023
Decision date	Aug 30, 2023
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medartis, Inc.</b>
Location	San Diego, CA, US
Contact	Chelsea Kozior
510(k) history	5 submissions · 5 cleared · 2005-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232324/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026