

**K222645 Treace Medical Concepts (TMC) Implant Fixation System**Nov 21, 2022  
81 days to decisionK222645 · Product code: JDR · Orthopedic  
Source: <https://www.510kdatabase.net/k222645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Sep 1, 2022
Decision date	Nov 21, 2022
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Treace Medical Concepts</b>
Location	Ponte Vedra, FL, US
Contact	Brittany Grochala
510(k) history	5 submissions · 5 cleared · 2022-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222645/> 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 25, 2026