

**K242356 TIDAL Fusion Cage System**Mar 24, 2025  
228 days to decisionK242356 · Product code: **SAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k242356/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ankle Fusion Cage (SAI)
Date received	Aug 8, 2024
Decision date	Mar 24, 2025
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Restor3D, Inc.</b>
Location	Durham, NC, US
Contact	Brianna Prindle
510(k) history	6 submissions · 6 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242356/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026