

**K250637 VCFix Spinal System**May 30, 2025  
88 days to decisionK250637 · Product code: **NDN** · Orthopedic  
Source: <https://www.510kdatabase.net/k250637/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Mar 3, 2025
Decision date	May 30, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Amber Implants</b>
Location	The Hague, NL
Contact	Banafsheh Sajadi
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250637/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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