

**K220966 SINEFIX**Mar 8, 2023  
341 days to decisionK220966 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k220966/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 1, 2022
Decision date	Mar 8, 2023
Days to decision	341 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BAAT Medical Products B.V.</b>
Location	Rj Hengelo, NL
Contact	Jasper Springer
510(k) history	5 submissions · 5 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220966/> 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 14, 2026