

K254176 SINEFIXMar 16, 2026
83 days to decisionK254176 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k254176/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 23, 2025
Decision date	Mar 16, 2026
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k254176/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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