

K254306 Aevumed FENIX Suture AnchorMar 4, 2026
63 days to decisionK254306 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k254306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Dec 31, 2025
Decision date	Mar 4, 2026
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aevumed, Inc.
Location	Malvern, PA, US
Contact	Saif Khalil
Website	https://aevumed.com
510(k) history	7 submissions · 7 cleared · 2018-2026

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