

K253040 Aevumed FASE Suture AnchorOct 21, 2025
29 days to decisionK253040 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k253040/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 22, 2025
Decision date	Oct 21, 2025
Days to decision	29 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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