

K253027 Anchor with Fiber Wire and Disposable InserterMay 6, 2026
229 days to decisionK253027 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k253027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Sep 19, 2025
Decision date	May 6, 2026
Days to decision	229 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ortobio S.A.
Location	Maringá, BR
Contact	Arthur Murakami
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Pr Serviços Regulatórios Administrativos Ltda
Contact	Tatiana Jabor Botura

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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