

K252664 GMReis Suture AnchorsNov 4, 2025
74 days to decisionK252664 · Product code: **MBI** · Orthopedic
Source: <https://www.510kdatabase.net/k252664/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Aug 22, 2025
Decision date	Nov 4, 2025
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	GM Dos Reis Industria e Comercio Ltda.
Location	Campinas, BR
Contact	Guilherme Esteves Pontes
510(k) history	13 submissions · 13 cleared · 2020-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252664/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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