

K254188 Meniscus VersaflexFeb 19, 2026
58 days to decisionK254188 · Product code: **GAT** · Orthopedic
Source: <https://www.510kdatabase.net/k254188/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Dec 23, 2025
Decision date	Feb 19, 2026
Days to decision	58 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

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