

K253910 Stitch - Suture Wires and Tapes

Aug 22, 2026
257 days to decision

K253910 · Product code: **GAT** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253910/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Dec 8, 2025
Decision date	Aug 22, 2026
Days to decision	257 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	16 submissions · 16 cleared · 2020-2026