

K243905 Stitch Cerclage – Suture TapesAug 14, 2025
238 days to decisionK243905 · Product code: **JDQ** · Orthopedic
Source: <https://www.510kdatabase.net/k243905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cerclage, Fixation (JDQ)
Date received	Dec 19, 2024
Decision date	Aug 14, 2025
Days to decision	238 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/k243905/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026