

K252820 PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures (Calypso)Oct 3, 2025
29 days to decisionK252820 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Sep 4, 2025
Decision date	Oct 3, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PGLA90 Poly(glycolide-co-L-lactide) Surgical Sutures (Odysseus)

APPLICANT

Company	Internacional Farmac?utica S.A DE C.V
Location	Lerma, MX
Contact	Alejandro Leonardo von Mohr del Conde
510(k) history	1 submissions · 1 cleared · 2025-2025

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