

K160564 TroClose1200Nov 17, 2016
262 days to decisionK160564 · Product code: **GAM** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Feb 29, 2016
Decision date	Nov 17, 2016
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gordian Surgical, Ltd.
Location	Karmiel, IL
Contact	ZVI PEER
510(k) history	3 submissions · 3 cleared · 2016-2025

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