

**K253620 TroClose 1200**Dec 16, 2025  
28 days to decisionK253620 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253620/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Nov 18, 2025
Decision date	Dec 16, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gordian Surgical, Ltd.</b>
Location	Karmiel, IL
Contact	Eddie Shaw
510(k) history	3 submissions · 3 cleared · 2016-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Avio Medtech Consulting</b>
Contact	Matthieu Kirkland

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253620/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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