

**K221527 StitchKit**Feb 14, 2023  
264 days to decisionK221527 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	May 26, 2022
Decision date	Feb 14, 2023
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Origami Surgical Inc .</b>
Location	Madison, NJ, US
Contact	John Gillespie
510(k) history	2 submissions · 2 cleared · 2021-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221527/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026