

**K230311 HyperSuture**Nov 24, 2023  
294 days to decisionK230311 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230311/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Feb 3, 2023
Decision date	Nov 24, 2023
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Threadstone, LLC</b>
Location	Millersville, MD, US
Contact	Jeremy Clark
510(k) history	5 submissions · 5 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230311/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026