

**K191317 StitchKit**Jul 12, 2019  
58 days to decisionK191317 · Product code: **NBY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191317/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                       |
| Submission type       | Traditional  |
| Device classification | Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene (NBY) |
| Date received         | May 15, 2019   |
| Decision date         | Jul 12, 2019   |
| Days to decision      | 58 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Origami Surgical</b>               |
| Location       | Madison, NJ, US                       |
| Contact        | John Gillespie                        |
| 510(k) history | 2 submissions · 2 cleared · 2019-2021 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191317/> 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 27, 2026