

**K173644 Gazelle Polypropylene Suture and Delivery Device**Feb 15, 2018  
80 days to decisionK173644 · Product code: **GAW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173644/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Abbreviated   |
| Device classification | Suture, Nonabsorbable, Synthetic, Polypropylene (GAW) |
| Date received         | Nov 27, 2017  |
| Decision date         | Feb 15, 2018  |
| Days to decision      | 80 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Dura Tap, LLC</b>                  |
| Location       | Wayne, PA, US                         |
| Contact        | Ann R. Lee                            |
| 510(k) history | 2 submissions · 2 cleared · 2018-2018 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173644/> 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 31, 2026