

**K173335 Gazelle PTFE and Suture Delivery Device**Feb 8, 2018  
108 days to decisionK173335 · Product code: **NBY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k173335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Suture, Surgical, Nonabsorbable, Expanded, Polytetraflouroethylene (NBY)
Date received	Oct 23, 2017
Decision date	Feb 8, 2018
Days to decision	108 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/k173335/> 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