

**K163507 Triton Sponge System**Apr 25, 2017  
132 days to decisionK163507 · Product code: **PBZ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k163507/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Processing Device For Estimation Of External Blood Loss (PBZ)
Date received	Dec 14, 2016
Decision date	Apr 25, 2017
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gauss Surgical, Inc.,</b>
Location	Cupertino, CA, US
Contact	Artie Kaushik
510(k) history	6 submissions · 5 cleared · 2012-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163507/> 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 14, 2026