

**K983318 FIXATION SYSTEM**Mar 1, 1999  
161 days to decisionK983318 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k983318/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Sep 21, 1998
Decision date	Mar 1, 1999
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>General Surgical Innovations</b>
Location	Portola Valley, CA, US
Contact	FEROLYN T POWELL
510(k) history	14 submissions · 13 cleared · 1993-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k983318/> 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 July 4, 2026