

**K972109 SPACEMAKER SURGICALBALLOON  
DISSECTOR/EXPANDER**Nov 14, 1997  
162 days to decisionK972109 · Product code: **FZW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k972109/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Expander, Surgical, Skin Graft (FZW)
Date received	Jun 5, 1997
Decision date	Nov 14, 1997
Days to decision	162 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	CATHLEEN MANTOR
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/k972109/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated July 4, 2026