

**K952707 SILICONE ELASTOMER MALAR IMPLANT**Aug 28, 1995  
75 days to decisionK952707 · Product code: **FZE** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k952707/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Nose, Internal (FZE)
Date received	Jun 14, 1995
Decision date	Aug 28, 1995
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Spirit Ridge Technologies</b>
Location	Seattle, WA, US
Contact	KATHY RICHRDSON
510(k) history	5 submissions · 5 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952707/> 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 5, 2026