

**K935939 GAUZE FLUFF**Jan 14, 1994  
32 days to decisionK935939 · Product code: **EFQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k935939/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal (EFQ)
Date received	Dec 13, 1993
Decision date	Jan 14, 1994
Days to decision	32 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mcneil Healthcare, Inc.</b>
Location	Waterford, CT, US
Contact	TIMOTHY D MCNEIL
510(k) history	19 submissions · 19 cleared · 1994-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k935939/> 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 6, 2026