

**K895086 GAUZE SPONGE**Oct 23, 1989  
76 days to decisionK895086 · Product code: **EFQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k895086/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gauze/sponge, Internal (EFQ)
Date received	Aug 8, 1989
Decision date	Oct 23, 1989
Days to decision	76 days
Third-party review	No

**APPLICANT**

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Company	<b>Keilei Intl., Inc.</b>
Location	Dover, NJ, US
Contact	ALBERT SHEN
510(k) history	5 submissions · 5 cleared · 1989-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895086/>; 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 7, 2026