

**K010675 ENSIL FABRIC**May 30, 2001  
85 days to decisionK010675 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k010675/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Mar 6, 2001
Decision date	May 30, 2001
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gottfried Medical, Inc.</b>
Location	Mchenry, IL, US
Contact	BRENT M GOTTFRIED
510(k) history	2 submissions · 2 cleared · 1982-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010675/> 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 1, 2026