

**K941197 SILK\*SKIN SCAR TREATMENT**Aug 11, 1994  
150 days to decisionK941197 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k941197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Mar 14, 1994
Decision date	Aug 11, 1994
Days to decision	150 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Puritas Health Care, Inc.</b>
Location	Brookfield, CT, US
Contact	THOMAS P DI MAIO
510(k) history	24 submissions · 22 cleared · 1991-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941197/> 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 May 26, 2026