

K960254 SILGEL TOPICAL GEL SHEETApr 2, 1996
76 days to decisionK960254 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k960254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jan 17, 1996
Decision date	Apr 2, 1996
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Rofil Medical USA, Inc.
Location	Laguna Hills, CA, US
Contact	WILLIAM E STOVALL
510(k) history	1 submissions · 1 cleared · 1996-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k960254/> Data sourced from FDA 510(k) public records (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. - Generated July 5, 2026