

K914701 SIL-KJan 31, 1992
105 days to decisionK914701 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k914701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Oct 18, 1991
Decision date	Jan 31, 1992
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Degania Silicone , Ltd.
Location	Emek Hayarden, IL
Contact	BETTE LUBIN
510(k) history	19 submissions · 17 cleared · 1988-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914701/> 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 May 14, 2026