

K941125 NOVAGEL SILICONE GEL SHEETINGMay 31, 1994
83 days to decisionK941125 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k941125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Mar 9, 1994
Decision date	May 31, 1994
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Brennen Medical, Inc.
Location	St, Paul, MN, US
Contact	JEFFREY M WILLIAMS
510(k) history	17 submissions · 16 cleared · 1994-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k941125/> 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 June 30, 2026