

**K981902 SPENCO SILICONE GEL SHEET**Jun 25, 1998  
24 days to decisionK981902 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k981902/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jun 1, 1998
Decision date	Jun 25, 1998
Days to decision	24 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Spenco Medical Corp.</b>
Location	Mchenry, IL, US
Contact	BRENDA HUNT
510(k) history	10 submissions · 9 cleared · 1979-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981902/> 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