

**K003948 EPI-DERM SILICONE GEL SHEETING**Jan 29, 2001  
39 days to decisionK003948 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k003948/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Dec 21, 2000
Decision date	Jan 29, 2001
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biodermis Corp.</b>
Location	Las Vegas, NV, US
Contact	JEFF S SCHLEUING
510(k) history	5 submissions · 5 cleared · 1994-2001

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