

K991604 EPI-FOAM SILICONE SHEETINGJun 9, 1999
30 days to decisionK991604 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k991604/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	May 10, 1999
Decision date	Jun 9, 1999
Days to decision	30 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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