

K992146 SCARAIID SILICONE GEL SHEETINGJul 30, 1999
36 days to decisionK992146 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k992146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jun 24, 1999
Decision date	Jul 30, 1999
Days to decision	36 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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