FDA 510(k) Premarket Notification

K913140 SILICONE GEL SHEETING

CLEARED

Sep 30, 1991
76 days to decision

K913140 · Product code: **MDA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k913140/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jul 16, 1991
Decision date	Sep 30, 1991
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cui Corp.**
Location	Santa Barbara, CA, US
Contact	ELLEN DUKE
510(k) history	7 submissions · 7 cleared · 1990-1991

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k913140/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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