FDA 510(k) Premarket Notification

K914701 SIL-K

CLEARED

Jan 31, 1992
105 days to decision

K914701 · Product code: **MDA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k914701/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Oct 18, 1991
Decision date	Jan 31, 1992
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Degania Silicone , Ltd.**
Location	Emek Hayarden, IL
Contact	BETTE LUBIN
510(k) history	19 submissions · 17 cleared · 1988-2026