

K964846 IMPLATECH RP MEDICAL GRADE SILICONE GEL SHEETINGFeb 12, 1997
71 days to decisionK964846 · Product code: **MDA** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k964846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Dec 3, 1996
Decision date	Feb 12, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Implantech Associates, Inc.
Location	Washington, DC, US
Contact	EDWARD M BASILE, ESQ.
510(k) history	41 submissions · 40 cleared · 1989-2020

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