FDA 510(k) Premarket Notification

K012419 CONFORM SHEETING, MODEL IGEL

CLEARED

Oct 24, 2001
86 days to decision

K012419 · Product code: **MDA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k012419/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jul 30, 2001
Decision date	Oct 24, 2001
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Implantech Associates, Inc.**
Location	Washington, DC, US
Contact	STEPHEN MEADE
510(k) history	41 submissions · 40 cleared · 1989-2020