

**K012419 CONFORM SHEETING, MODEL IGEL**Oct 24, 2001  
86 days to decisionK012419 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k012419/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012419/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026