

**K013732 GELZONE**Feb 7, 2002  
90 days to decisionK013732 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k013732/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Nov 9, 2001
Decision date	Feb 7, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013732/> 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