

**K041704 NEWGEL AND NEWGEL PLUS E**Oct 17, 2005  
481 days to decisionK041704 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k041704/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jun 23, 2004
Decision date	Oct 17, 2005
Days to decision	481 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Newmedical Technology, Inc.</b>
Location	Waukesha, WI, US
Contact	HAITHAM MATLOUB
510(k) history	3 submissions · 3 cleared · 2003-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041704/> 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 May 20, 2026