

**K002109 OLEEVA FOAM**Aug 31, 2000  
50 days to decisionK002109 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k002109/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Jul 12, 2000
Decision date	Aug 31, 2000
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio Med Sciences, Inc.</b>
Location	Bethlehem, PA, US
Contact	MARK E DILLON
510(k) history	10 submissions · 10 cleared · 1991-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002109/> 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 July 3, 2026