

**K143349 Gynomunal**Sep 16, 2015  
296 days to decisionK143349 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k143349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Nov 24, 2014
Decision date	Sep 16, 2015
Days to decision	296 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Polichem S.A</b>
Location	Rockville, MD, US
Contact	Daria Mari
510(k) history	3 submissions · 3 cleared · 2009-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143349/> 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 4, 2026