

**K101348 AGACHAMBER SPACER**Apr 29, 2011  
351 days to decisionK101348 · Product code: **NVP** · Anesthesiology  
Source: <https://www.510kdatabase.net/k101348/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Holding Chambers, Direct Patient Interface (NVP)
Date received	May 13, 2010
Decision date	Apr 29, 2011
Days to decision	351 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aga Plastic Ind. Com. Ltda.</b>
Location	Great Neck, NY, US
Contact	MARIA F GRIFFIN
510(k) history	2 submissions · 2 cleared · 1999-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101348/> 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 24, 2026