

**K101233 SAFE&apos;N&apos;SOUND PASSIVE DELIVERY SYSTEM**Feb 18, 2011  
291 days to decisionK101233 · Product code: **MEG** · General Hospital  
Source: <https://www.510kdatabase.net/k101233/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Syringe, Antistick (MEG)
Date received	May 3, 2010
Decision date	Feb 18, 2011
Days to decision	291 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rexam Pharma</b>
Location	Buffalo Grove, IL, US
Contact	JEFFREY BURRIS
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101233/> 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 19, 2026