

**K122122 REGEN SPRAY APPLICATOR,**Nov 9, 2012  
115 days to decisionK122122 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k122122/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jul 17, 2012
Decision date	Nov 9, 2012
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Regen Lab SA</b>
Location	Montreal, CA
Contact	GUY FORTIER
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122122/> 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 9, 2026