

**K051291 NON-STERILE SURGICAL MASK**Sep 20, 2005  
125 days to decisionK051291 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k051291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 18, 2005
Decision date	Sep 20, 2005
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>A.R. Medicom, Inc.</b>
Location	Quebec, H4m 2n5 Canada, CA
Contact	LUC TREPANIER
510(k) history	3 submissions · 3 cleared · 1994-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k051291/> 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 28, 2026