

**K131804 REMEL XPECT FLU A&B**Jul 12, 2013  
23 days to decisionK131804 · Product code: **GNX** · Microbiology  
Source: <https://www.510kdatabase.net/k131804/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Antigens, Cf (including Cf Control), Influenza Virus A, B, C (GNX)
Date received	Jun 19, 2013
Decision date	Jul 12, 2013
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Remel, Inc.</b>
Location	Lenexa, KS, US
Contact	CINDY KNAPP
510(k) history	17 submissions · 17 cleared · 1994-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131804/> 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 1, 2026