

**K080956 MODIFICATION TO VF GEL PLUS**Apr 25, 2008  
22 days to decisionK080956 · Product code: **MIX** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k080956/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Apr 3, 2008
Decision date	Apr 25, 2008
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Coapt Systems, Inc.</b>
Location	Palo Alto, CA, US
Contact	LINDA RUEDY
510(k) history	17 submissions · 17 cleared · 2002-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080956/> 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 20, 2026