

**K081816 VOCALIS AND VOCALIS SM**Jan 5, 2009  
193 days to decisionK081816 · Product code: **MIX** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k081816/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Jun 26, 2008
Decision date	Jan 5, 2009
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cytophil, Inc.</b>
Location	Whitefish Bay, WI, US
Contact	Greg Johnson
510(k) history	8 submissions · 8 cleared · 2008-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081816/> 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 18, 2026