

**K121351 SINUS DILATION SYSTEM**Aug 29, 2012  
117 days to decisionK121351 · Product code: **LRC** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k121351/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ent Manual Surgical (LRC)
Date received	May 4, 2012
Decision date	Aug 29, 2012
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Entrigue Surgical, Inc.</b>
Location	San Antonio, TX, US
Contact	GABRIELE G NIEDERAUER, PH.D.
510(k) history	4 submissions · 4 cleared · 2007-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121351/> 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 8, 2026