

**K113126 ACRYLIC HERBST APPLIANCE**Jul 17, 2013  
632 days to decisionK113126 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k113126/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Oct 24, 2011
Decision date	Jul 17, 2013
Days to decision	632 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gergens Orthodontic Lab</b>
Location	Dunlap, IL, US
Contact	KAREN E WARDEN, PHD
510(k) history	2 submissions · 2 cleared · 2013-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113126/> 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 4, 2026