

K130504 ASA ORAL APPLIANCESOct 18, 2013
233 days to decisionK130504 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k130504/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Feb 27, 2013
Decision date	Oct 18, 2013
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Sleep Association
Location	Chesterland, OH, US
Contact	KAREN E WARDEN, PHD
510(k) history	1 submissions · 1 cleared · 2013-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k130504/> Data sourced from FDA 510(k) public records (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. - Generated June 8, 2026