

**K140278 SOMNODENT FUSION, CLASSIC**Jun 20, 2014  
137 days to decision

K140278 · Product code: LRK · Dental

Source: <https://www.510kdatabase.net/k140278/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Anti-snoring (LRK)
Date received	Feb 3, 2014
Decision date	Jun 20, 2014
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary
Other names	SOMNODENT FUSION, FLEX

**APPLICANT**

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Company	<b>Somnomed, Inc.</b>
Location	Denton, TX, US
Contact	KATHRYN A JAYNE
510(k) history	10 submissions · 10 cleared · 2008-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140278/>; 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 26, 2026