

**K102909 SOMNOBRUX SPLINTS**Dec 13, 2011  
438 days to decisionK102909 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k102909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Oct 1, 2010
Decision date	Dec 13, 2011
Days to decision	438 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Somnomed, Inc.</b>
Location	Denton, TX, US
Contact	BRADLEY SOUTHWORTH
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/k102909/> 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