

**K212767 SleepRight Select-Comfort Dental Guard**Dec 22, 2021  
113 days to decisionK212767 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k212767/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Aug 31, 2021
Decision date	Dec 22, 2021
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Splintek, Inc.</b>
Location	Lenexa, KS, US
Contact	Thomas W. Brown
510(k) history	5 submissions · 5 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212767/> 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