

**K243516 Remi Custom Night Guard**Feb 10, 2025  
89 days to decisionK243516 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k243516/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Nov 13, 2024
Decision date	Feb 10, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Grindguard, Inc.</b>
Location	San Francisco, CA, US
Contact	Oscar Adelman
510(k) history	2 submissions · 2 cleared · 2025-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Prime Path Medtech</b>
Contact	Jennifer Day

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243516/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026