

**K250743 Remvia NightGuard**Dec 5, 2025  
269 days to decisionK250743 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k250743/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Mar 11, 2025
Decision date	Dec 5, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Remvia</b>
Location	St. Louis, MO, US
Contact	Nephi Zufelt
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250743/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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