FDA 510(k) Premarket Notification

K243516 Remi Custom Night Guard

CLEARED

Feb 10, 2025
89 days to decision

K243516 · Product code: **MQC** · Dental
Source: https://www.510kdatabase.net/k243516/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Jennifer Day

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