FDA 510(k) Premarket Notification

K251778 Remi Custom Night Guard

CLEARED

Oct 17, 2025
129 days to decision

K251778 · Product code: **OBR** · Dental
Source: https://www.510kdatabase.net/k251778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Jun 10, 2025
Decision date	Oct 17, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Remi**
Location	San Francisco, CA, US
Contact	Oscar Adelman
510(k) history	1 submissions · 1 cleared · 2025-2025

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