

K253641 Owl Night GuardFeb 26, 2026
99 days to decisionK253641 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k253641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Nov 19, 2025
Decision date	Feb 26, 2026
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Owl Dental Lab, Inc.
Location	San Leandro, CA, US
Contact	Jason Huang
510(k) history	1 submissions · 1 cleared · 2026-2026

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253641/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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