

K221369 FBCC Night GuardNov 18, 2022
190 days to decisionK221369 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k221369/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	May 12, 2022
Decision date	Nov 18, 2022
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fbcc, Inc.
Location	Los Angeles, CA, US
Contact	Pablo Osorio
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Prime Path Medtech
Contact	Elisabeth Miller

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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