

**K252004 enCore Night Guard**Nov 25, 2025  
151 days to decisionK252004 · Product code: **OBR** · Dental  
Source: <https://www.510kdatabase.net/k252004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Jun 27, 2025
Decision date	Nov 25, 2025
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Encore Guards</b>
Location	Santa Ana, CA, US
Contact	Benjamin Li
510(k) history	2 submissions · 2 cleared · 2025-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252004/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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