

K211158 NTI ClenchGuardSep 17, 2021
151 days to decisionK211158 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k211158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Apr 19, 2021
Decision date	Sep 17, 2021
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Boyd Research, Inc.
Location	Solana Beach, CA, US
Contact	James Boyd
510(k) history	2 submissions · 2 cleared · 2020-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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