

K183315 CustMBite Dental GuardAug 23, 2019
266 days to decisionK183315 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k183315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Nov 30, 2018
Decision date	Aug 23, 2019
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dental Choice Holdings, LLC
Location	Louisville, KY, US
Contact	Ron Story
510(k) history	2 submissions · 2 cleared · 2019-2022

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