

K172452 BruxorJan 11, 2018
150 days to decisionK172452 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k172452/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Aug 14, 2017
Decision date	Jan 11, 2018
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sleep Specialties, LLC
Location	Las Vegas, NV, US
Contact	James S. Fallon
510(k) history	1 submissions · 1 cleared · 2018-2018

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