

K193577 SleepRight ProRx Custom Dental GuardJun 1, 2020
161 days to decisionK193577 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k193577/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Dec 23, 2019
Decision date	Jun 1, 2020
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Splintek, Inc.
Location	Lenexa, KS, US
Contact	Thomas W Brown
510(k) history	5 submissions · 5 cleared · 2017-2025

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