

K212706 SleepRight ProRx + Custom Dental Guard, SleepRight ProRx Custom Dental GuardDec 13, 2021
109 days to decisionK212706 · Product code: OBR · Dental
Source: <https://www.510kdatabase.net/k212706/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Aug 26, 2021
Decision date	Dec 13, 2021
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	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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