

K212448 NightGuard FlexNov 12, 2021
99 days to decisionK212448 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k212448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Aug 5, 2021
Decision date	Nov 12, 2021
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sprintray, Inc.
Location	Los Angeles, CA, US
Contact	Sara Moghtadernejad
510(k) history	9 submissions · 9 cleared · 2021-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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