

K210011 JS Dental Lab Mouth GuardJul 16, 2021
193 days to decisionK210011 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k210011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jan 4, 2021
Decision date	Jul 16, 2021
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ampower Dental Laboratories, LLC
Location	Hayward, CA, US
Contact	Dylan Hao
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Elexes Medical Consulting, LLC
Contact	Parul Chansoria

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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