

K212660 Smylio Invisible Clear AlignersSep 22, 2021
30 days to decisionK212660 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k212660/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aligner, Sequential (NXC)
Date received	Aug 23, 2021
Decision date	Sep 22, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smylio, Inc.
Location	Fremont, CA, US
Contact	Ren Menon
510(k) history	3 submissions · 3 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Prime Path Medtech
Contact	Breanne Butler

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

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