

K210652 6MS Invisible AlignerJun 2, 2021
90 days to decisionK210652 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k210652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Mar 4, 2021
Decision date	Jun 2, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sms Opco, LLC
Location	The Colony, TX, US
Contact	Bruce Page
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Qserve Group, Us, Inc.
Contact	Patsy J. Trisler

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

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