

K200214 3D PredictFeb 24, 2020
27 days to decisionK200214 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k200214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jan 28, 2020
Decision date	Feb 24, 2020
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3D Smile USA, Inc.
Location	Philadelphia, PA, US
Contact	Marina Domracheva
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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