

K211190 3M Clarity Aligners (3M Clarity Aligners-Force, 3M Clarity Aligners-Flex)Apr 23, 2021
2 days to decisionK211190 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k211190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Apr 21, 2021
Decision date	Apr 23, 2021
Days to decision	2 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3M Company, Unitek Orthodontic Products
Location	Saint Paul, MN, US
Contact	Yanine Garcia-Quezada
510(k) history	3 submissions · 3 cleared · 2021-2023

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211190/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026