

K231464 3M™ Clarity™ Aligners (3M™ Clarity™ Aligners-Force, 3M™ Clarity™ Aligners-Flex)May 22, 2023
3 days to decisionK231464 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k231464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 19, 2023
Decision date	May 22, 2023
Days to decision	3 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	Brittany Randolph
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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231464/>; 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