FDA 510(k) Premarket Notification

# K192119 3M Clarity Aligners

**CLEARED**

Sep 5, 2019
30 days to decision

K192119 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k192119/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Aligner, Sequential (NXC) |
| Date received | Aug 6, 2019 |
| Decision date | Sep 5, 2019 |
| Days to decision | 30 days |
| Third-party review | Yes |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **3M Company** |
| Location | White City, OR, US |
| Contact | Yanine Garcia-Quezada |
| Website | http://www.3m.com/ |
| 510(k) history | 331 submissions · 322 cleared · 1976-2025 |

## REGULATORY CONSULTANT

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|---|---|
| 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.net
Device record: https://www.510kdatabase.net/k192119/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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