FDA 510(k) Premarket Notification

# K212680 LuxCreo Clear Aligner System

**CLEARED**

May 31, 2022
280 days to decision

K212680 · Product code: **NXC** · Dental
Source: https://www.510kdatabase.net/k212680/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Aligner, Sequential (NXC) |
| Date received | Aug 24, 2021 |
| Decision date | May 31, 2022 |
| Days to decision | 280 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **LuxCreo, Inc.** |
| Location | Belmont, CA, US |
| Contact | Mike Yang |
| 510(k) history | 4 submissions · 4 cleared · 2022-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Ruscert Technology Co., Ltd.** |
| Contact | Ming-Yie Jan |

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