

K212680 LuxCreo Clear Aligner SystemMay 31, 2022
280 days to decisionK212680 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k212680/>**SUBMISSION DETAILS**

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

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