

K250343 LuxCreo Clear Aligner SystemApr 8, 2025
61 days to decisionK250343 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k250343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aligner, Sequential (NXC)
Date received	Feb 6, 2025
Decision date	Apr 8, 2025
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	LuxCreo, Inc.
Location	Belmont, CA, US
Contact	Tao Feng
510(k) history	4 submissions · 4 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250343/> 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 13, 2026