

K253282 ZSmile SystemFeb 3, 2026
127 days to decisionK253282 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k253282/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aligner, Sequential (NXC)
Date received	Sep 29, 2025
Decision date	Feb 3, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dror Orthodesign , Ltd.
Location	Jerusalem, IL
Contact	Orly Maor
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253282/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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