

**K252931 Invisalign® Palatal Expander System**Oct 23, 2025  
38 days to decisionK252931 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k252931/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aligner, Sequential (NXC)
Date received	Sep 15, 2025
Decision date	Oct 23, 2025
Days to decision	38 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Align Technology, Inc.</b>
Location	San Jose, CA, US
Contact	Ahanitha Ashok
510(k) history	11 submissions · 11 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252931/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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