

**K250739 Primeprint Direct Aligner**Nov 7, 2025  
241 days to decisionK250739 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k250739/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Mar 11, 2025
Decision date	Nov 7, 2025
Days to decision	241 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dreve Dentamid GmbH</b>
Location	Unna, DE
Contact	Anke Hüttenbrauck
510(k) history	6 submissions · 6 cleared · 2017-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250739/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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