

**K242892 Cristaline Aligners Z FLX**Dec 19, 2024  
87 days to decisionK242892 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k242892/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 23, 2024
Decision date	Dec 19, 2024
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cristaline Aligners GmbH</b>
Location	Pforzheim, DE
Contact	Boris Simnovski
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Trisler Consulting (Db)</b>
Contact	Patsy Trisler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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